federal register

Wednesday
November 12, 1980

Part V

Department of Agriculture

Food and Nutrition Service

Special Supplemental Food Program for Women, Infants and Children

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 246

Special Supplemental Food Program for Women, Infants and Children

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rule.

SUMMARY: These final regulations set forth the requirements for the types and quantities of supplemental foods to be provided under the Special Supplemental Food Program for Women, Infants and Children (WIC Program). These final rules are in compliance with Section 3 of Public Law 95–627 which amends Section 17 of the Child Nutrition Act of 1966 and extends the authorization for the WIC Program through FY 1982.

EFFECTIVE DATE: This regulation is effective November 12, 1980, and must be implemented within 12 months of the publication date.

FOR FURTHER INFORMATION CONTACT: Darrel E. Gray, Acting Director, Supplemental Food Programs Division, Food and Nutrition Service, U.S. Department of Agriculture, Washington, D.C. 20250, (202) 447–8206.

The Final Impact Statement describing the options considered in developing this final rule and the impact of implementing each option is available on request from the above named individual.

SUPPLEMENTARY INFORMATION:

Introduction

On November 30, 1979, the Department published a notice of proposed rulemaking (44 FR 69254–69270) to revise the regulations pertaining to the types and quantities of supplemental foods provided through the WIC Program.

In developing the proposal, the Department sought public participation in policy development by holding public hearings, attending Regional, State and local meetings, requesting public comments on cereal issues, convening a food package advisory panel, and requesting input from the National Advisory Council on Maternal, Infant and Fetal Nutrition.

The Department invited written comments in favor of or in objection to the proposed regulations, and comments recommending alternatives not considered in the proposed regulations. In response to the proposed rulemaking, the Department received 1,074 comment letters from Congressional offices, State agencies, local agencies, government offices, interest groups, the food industry, universities and colleges, participants and the general public. The Department carefully analyzed these 1,074 letters which contained comments supporting and opposing proposed changes in the food package regulations and suggesting changes in the food package regulations which were not considered in the proposal. In some instances comments were vague and many comment letters incorporated several subjects. All numbers of comments relating to specific food package issues are approximations.

The substantive comments received and the actions taken by the Department are discussed in the following preamble. For the purpose of clarity, the food package categories are first discussed briefly, and then specific food package issues are discussed according to food item rather than food package.

This preamble articulates the basis and purpose behind significant changes from the November 30, 1979, proposal. In addition, provisions of the proposed regulations which received a substantial number of comments are discussed. The reasons supporting provisions of the proposed regulations were carefully examined in light of the comments to determine the continued applicability of the justifications. Unless otherwise stated, or unless inconsistent with the final rules or this preamble, the rationales contained in the preamble to the proposed regulations should be regarded as a basis for the pertinent final rules. Therefore, a thorough understanding of the rationales for the final regulations may require reference to the preamble of the November 30, 1979, proposal.

General Discussion. A comprehensive review of comments on the proposed rules in general and on each provision of the proposed rules revealed certain patterns of concern. Commenters repeatedly stated that the WIC Program should remain a supplemental food program, with emphasis on nutrition education to improve eating habits. Additionally, commenters consistently expressed concern about the complexity and costs of the proposed changes. Commenters were concerned that the proposed food packages would be too confusing for local personnel, vendors and participants and create an administrative burden. Commenters believed that the delineation of more food packages and addition of new types of foods would add to administrative problems. The general belief was that the simpler the Program, the better it is understood, and therefore, the easier it is administered and monitored. Additional food costs and/or administrative costs were also of concern to commenters because increased costs would result in fewer participants being served.

The Department's philosophy about the WIC Program is consistent with these concerns expressed by commenters. The WIC Program is aimed at providing supplemental foods to assist participants in obtaining an adequate diet. The foods provided are not intended to provide a complete diet but to provide good sources of nutrients lacking in the diets of the target population. Nutrition education is provided through the WIC Program in order to assist participants in choosing foods, which in addition to the supplemental foods provided in the food package, meet their total dietary needs. Additionally, nutrition education is intended to assist participants in developing sound dietary habits which can be maintained after participation in WIC is terminated. The supplemental nature of the WIC Program and the interrelatedness of the food package with nutrition education were important factors considered in developing this final rule.

The WIC Program serves infants, children, pregnant women, breastfeeding women and non-breastfeeding postpartum women. These categories of participants have differing nutritional needs. Furthermore, participants have different ethnic, cultural and regional backgrounds resulting in varied food preferences. The food packages prescribed in this regulation take into account the different nutritional needs and food preferences of participants while at the same time taking into account feasibility of implementation. The Department realizes that the more complex the Program becomes the more difficult it is to administer and has taken this into account in making its final decisions regarding the food packages.

Cost was another factor taken into consideration in developing the food packages prescribed in this regulation. The WIC Program serves approximately 2.1 million women, infants and children of the estimated 9.1 million potentially eligible on the basis of income. The Department is committed to serving the largest number of eligible persons with the funds available for the Program and realizes that a major increase in the total cost of the food packages would substantially affect the number of participants the WIC Program could serve. Commenters were also concerned

about any increase in cost that changes in the food packages would create.

Therefore, the Department decided to stay within the average cost range of the August 1977 food packages. Although there are additional foods in certain packages, the reduction of food quantities in certain packages offsets these cost increases. All changes combined result in a total food package cost that is virtually the same as the previous food packages.

The Department has developed nutritionally appropriate food packages while at the same time containing food costs and administrative burdens. This final regulation responds to WIC participants' needs, administrators' concerns and Program goals.

Sugar, Salt and Fat. Section 3 of Public Law 95–627 specified that, to the degree possible, the Secretary shall assure the fat, sugar and salt content of the prescribed foods is appropriate. In accordance with this legislative mandate, some changes have been made in the kinds and quantities of foods allowed in the WIC Program.

Sugar

Several recent publications have emphasized the need for concern about the amount of sugar in the American diet. The report of the American Society for Clinical Nutrition (*1*) concluded that "evidence is convincing that sucrose, especially when consumed frequently throughout the day, is the dietary component that is most conductive to . . . caries." This report concludes that "reduction in the frequency of sucrose consumption results in reduced dental caries without known risk."

The "Evaluation of Sucrose as a Food Ingredient" prepared for HEW by the Federation of American Societies for Experimental Biology (FASEB) concluded that, "Reasonable evidence exists that sucrose is a contributor to the formation of dental caries when used at the levels that are now current and in the manner practiced." (*2*)

The association between sugar consumption and dental caries was identified as far back as the 18th Century. Thomas Berdmore, dentist to King George III, wrote "* * * where sugar, tea, coffee and sweetmeats are used in excess, the people at an early age are remarkable for the badness of their teeth."(*3*) Nizel has summarized the major studies on nutrition and dental health and concludes, "Wartime restrictions on sugar consumption were associated with dramatic reductions in the activity of dental decay." Nizel also noted that "The most dramatic demonstration of the importance of added sugar in the causation of dental caries was made in a study in which patients used a variety of sugar supplements over periods of one or more years. Clear-cut evidence was produced of a striking relationship between the addition of sugar to the diets and the amount of dental decay which occurred during the experimental periods."(*4*)

The evidence from the literature indicates there is a strong association between sugar consumption and dental caries. However, some commenters suggested dental caries were not a serious concern. For example, one commenter quoted the FASEB report which states that "other than the contribution made to dental caries, there is no clear evidence in the available information on sucrose that demonstrates a hazard to the public when used at the levels that are now current and in the manner now practiced."(*5*)

The Department believes that dental caries are one of the most significant public health problems of children. The Department of Health and Human Services (DHHS) estimates that $13.3 billion was spent in 1978 for dental care.(*6*) The Department would be remiss in not attempting to address this problem given that the WIC Program is aimed at improving the health and well-being of participants. One approach for dealing with dental caries is to ensure moderaton in the sugar content of the food package.

Several commenters pointed out that sugar plays a role in the development of tooth decay but that the amount of sugar in a particular food is but one of many factors involved in dental caries. In their comments, the Kellogg Company stated that "combinations of cereal and milk have a fluid consistency and do not remain in the mouth for sufficient lenghts of time to be a cause of dental caries."(*7*) The Company stated that since the majority of presweetened cereals are eaten with milk, such cereals cannot be implicated in the formation of caries. However, the Company's own marketing research data indicate that ⅙ of children aged 1–5 consume such cereals without milk.(*8*) The Department believes that it is important to consider the effects of such cereal consumption on this substantial proporation of children, since other studies have implicated presweetened cereal consumption with the formation of dental caries.(*9*) While the studies cited by Kelloggs did not illustrate this association, these studies did not control for the frequency of consumption or for the types of other foods in the diets of the children studied.(*10–13*)

The Department recognized that the development of dental caries involves a multiple etiology. The FASEB report noted that although sugar is a contributor to tooth decay, the frequency of sugar consumption, the stickiness of the sugar containing foods and whether the foods are consumed with meals or between meals are also factors to consider.

The Department is not suggesting that limiting consumption of only one or two foods would solve the problem of tooth decay. However, since the total sugar in the diet does influence dental caries, the Department is attempting to moderate sugar consumption in two ways. First, this will be done directly by moderating the level of sugar in the food package. Second, the nutrition education provided in WIC will stress the importance of wise food choices of items not included in the food package.

Several commenters did not dispute the need to decrease the sugar content of the food package but felt cereals were unnecessarily singled out as the main source of sugar. Two commenters noted that fruit juices have more sugar than cereals. Some commenters felt this distinction between cereal and other WIC foods was an arbitrary distinction between "natural" and "artificial" sources of sugar.

The Department is not suggesting that there is any difference in the biological effect between naturally occuring sugar and sugar used in processing. The goal of the final regulations is to reduce the level of sugar in the total package. In order to do this, the Department reviewed the evidence on sources of sugar in the U.S. diet.

Sugar consumption per capita in the U.S. has increased by one-third since 1909–1913. The biggest increase in sugar has been from processed foods. In 1909–1913 only 25 percent of the sugar consumed was from processed foods or beverages. In 1978, over 70 percent of the sugar consumed by the civilian population was in commercially prepared foods or beverages.(*14*) An increasingly large proportion of refined sugar is consumed in processed foods.

At the same time, the amount of naturally occurring sugar consumed has remained almost constant between 1909–1913 (51 g) and 1979 (58 g.)(*15*) These data would indicate that increased sugar in the American diet has been due mainly to consumption of processed foods. One author has noted that "consumers have much less control over the amount of sugar in their diets now than earlier in the century."(*16*)

Since the biggest increase in sugar consumption has been from processed foods, a decrease in consumption of these sources of sugar seems warranted in an effort to reduce sugar consumption

in general. This is consistent with the Surgeon General's report,(*17*) and the 1980 RDA's(*18*) which suggest cutting down on the sources of excess sugar in the diet.

The Department recognizes that the juice in the food package also contains sugar. Juice contains approximately 3.5 grams of sugar per fluid ounce [a] as compared to 0 to 23.0 grams of sugar per 1-ounce serving of cereal. Since a serving size of juice is generally 4 fluid ounces, juice will provide more sugar per serving than a 1-ounce serving of some cereals. However, the sugar content of juice cannot be easily reduced since sugar is an inherent component of the product. In cereals, on the other hand, much of the sugar is added and can be reduced without simultaneously reducing other nutrients. For example, the range of sugar content in cereals containing 45 percent of the USRDA for iron is 0.2 to 13.3 grams of sugar per ounce of cereal. A cereal containing only 6.0 grams of sugar per ounce contains exactly the same amount of iron as the highest level (13.3 g) sugar cereals.

In addition, highly sugared cereals tend to be more expensive than cereals containing less sugar. As the sugar content of the cereals increases, the average cost of the product also increases. While consumers may choose to add their own table sugar to the cereals authorized by WIC, this is a conscious decision made by the consumer, as well as a more economical way to buy sugar. Therefore, if highly sugared cereals are allowed, the food packages themselves are inconsistent with the goal of teaching participants economical food buying patterns.

The Department proposed setting a maximum limit for sugar in cereals in WIC food packages of 6 grams per 1-ounce serving. Commenters (490) were overwhelmingly in favor of the suggested limit. Many commenters (52) suggested a more stringent limit on sugar than the one proposed. However, there were a minority of commenters (101) including some State (14) and local (53) agencies, the Sugar Association and cereal companies, who opposed the sugar limit. Four of the industry commenters believed the sugar limit of 6 grams per ounce was chosen in an arbitrary and capricious manner. These commenters pointed out that in the recent competitive foods regulation issued by the Department, the Department declined to set a specific sugar limit for individual foods. (*19*) However, in the competitive foods rule, the Department was restricting the sale of foods of minimal nutritional value sold in competition with school lunch. The Department was dealing with all food items, for many of which there is incomplete or inadequate information on the sugar content. However, in the present regulation we are dealing with a limited range of foods on which we do have complete information on sugar. Of primary importance is the fact that cereal manufacturers have made complete food composition information about their products available. Thus, the Department knows the range of sugar content of cereals in general as well as the sugar content of each individual cereal.

There does not appear to be a clear cut-off point to differentiate low sugar cereals from high sugar cereals. Based on information collected from manufacturers, the sugar content of cereals available in the marketplace ranges from 0 to 23.0 grams of sugar per dry ounce of cereal (80 percent by weight). In cereals containing at least 45 percent of the USRDA for iron, the range is somewhat narrower with sugar levels between 0 and 13.3 grams per dry ounce of cereal (47 percent by weight). Sugar as used in this regulation means "sucrose and other sugars." This is the terminology the industry uses to label cereals.

The majority of commenters who recommended a maximum level of sugar for cereals authorized in the WIC Program recommended that this level be established at 15 or 20 percent. Percentage figures were often used to express the recommended level of sugar because they are most easily understood, but for practical purposes they must be converted to correspond to the figures used in nutrition labeling so that information found on cereal packages can be used to identify acceptable cereals. The converted percentages for 15 and 20 percent are, respectively, 4.25 and 5.67 grams of sugar per ounce of cereal, or, rounded to whole numbers, 4 and 6 grams per ounce. These figures are similar to the recommendation of the food package advisory panel that a maximum of 6 grams of sugar per ounce of cereal be allowed.

The Department relied on commenters, the food package advisory panel, the National Advisory Council on Maternal, Infant and Fetal Nutrition and the scientific literature in establishing the cereal sugar limit.

Although the Department found a consistent theme throughout the scientific literature that sugar consumption in the U.S. population should be reduced, it was difficult to suggest a single percentage limitation that could be used for all foods. The recommendations from the scientific literature that sugar should be decreased refer to reduction of sugar in the total diet. However, in order to reduce the daily intake of dietary sugar, it follows that either the sugar content of specific foods eaten must be decreased or the consumption of these foods must be decreased. Given the wide range of sugar content of cereals (0 to 81 percent by weight) and the fact that the major increase in per capita sugar consumption in the U.S. has been from processed foods, it appeared cereals would be a logical point to moderate the sugar content of the food packages. It should be emphasized again that the amount of sugar allowed in the authorized cereals does not affect the levels of other nutrients in the product.

Based on suggestions from commenters and members of the food package advisory panel, it was possible to identify a range within which the sugar level of cereals should fall. The consensus from these two sources on the sugar issue is clear; the sugar content should be decreased to 4 to 6 grams per 1-ounce serving of cereal.

The Department, therefore, has decided to accept the least restrictive limit recommended by the commenters which also corresponds to that suggested by the food package advisory panel. The maximum level of sugar allowed in cereals authorized for use in the WIC Program shall be 6 grams of sugar per ounce of dry cereal, which is equal to a level of 21 percent by weight. This decision reflects the views expressed in the majority of public comments received, is consistent with the food package advisory panel's recommendations, and is consistent with the overall purpose of the Program.

Several commenters suggested that individuals would probably add more sugar to cereals than is normally present in the presweetened product.

This statement assumes that such individuals would not attempt to change behavior patterns, even given the presentation of reasons through nutrition education for the reduction of sugar in the diet. However, such nutrition education efforts are negated if the allowable cereals include those already presweetened.

In conjunction with the sugar limit on cereals, the Department has also decided to eliminate the provision of flavored milk from the food packages. Seventy-eight commenters requested the deletion of flavored milk from the food packages because it also contains added sugar. The commenters indicated that providing flavored milk would be

[a] Source: USDA Handbook No. 8. Based on sugar contained in orange juice, unsweetened, canned.

contrary to nutrition education and the Department's proposal to limit sugar in the food package. No commenters expressed support for its inclusion. There is further discussion of flavored milk in the section of the preamble on flavored milk.

Salt (Sodium)

Several recent reports have examined the association between diet and disease, specifically the over consumption of sodium. Sodium is a naturally occurring factor in many foods, but is also a principal component of salt; salt is about 40 percent sodium. Thus diets can be high in sodium if they contain certain foods naturally high in sodium, or if they contain high levels of salt or both. The American Society for Clinical Nutrition in its symposium report "The Evidence Relating Six Dietary Factors to the Nation's Health" (*20*) found a strong association between salt and hypertension. The Surgeon General's report, "Disease Prevention and Health Promotion; Federal Programs and Prospects," (*21*) recommends reduction of salt intake for the general U.S. population. The Committee on Nutrition of the American Academy of Pediatrics in its 1974 Statement (*22*) indicated that there is a reasonable possibility that a low salt intake begun early in life and continued thereafter may to some extent protect children who are at risk of developing hypertension later in life.

The National Academy of Sciences Food and Nutrition Board's (FNB) recent publication, "Toward Healthful Diets"(*23*) makes a similar recommendation on sodium intake. The Board states: "sodium chloride intakes of many people in this country are excessive, particularly in the 15 percent of the American population at risk for hypertension. There is no reason to believe that reduction of sodium chloride intake to levels of 3 grams per day would be harmful for healthy persons and it may be helpful for the prevention of hypertension in susceptible individuals." In the latest edition of the "Recommended Dietary Allowances" published in January 1980,(*24*) the Food and Nutrition Board states that there are no known benefits of excessive salt consumption to a healthy person. The new text also includes estimated Safe and Adequate Intakes for some nutrients, inlcuding sodium, about which scientific data are less complete than for the 17 nutrients for which precise allowances have been established. The board cautions, "These suggested intakes must be regarded as more tentative and evolutionary than the RDA. They are presented as ranges of intake because the available data do not permit the definition of one intake for these nutrients." In spite of these limitations, the Safe and Adequate Intakes provide the most specific guidance to date. The recommended levels for various age groups in the population inlcude: 115 to 750 mg. sodium per day during the first year of life, 325 to 1350 mg. sodium per day for 1 to 5 year olds, 1169 to 3369 mg. sodium per day for pregnant women, and 1100 to 3300 mg. per day for non-pregnant women.

The safe and adequate levels were used as the standard to assess the sodium content of the WIC food packages when these regulations were proposed. It was clear then that the amount of sodium in the package for children exceeded the suggested range. Calculations done to determine the highest possible sodium content of the food packages [b] showed that such a package for pregnant and breastfeeding women would contain approximately 2470 mg. of sodium and for post partum women, 2140 mg. of sodium. Both of these values fall within the ranges suggested by the Food and Nutrition Board. However, the highest possible sodium value for the 1 to 5 year olds (2245 mg.) in such a package is well above the FNB safe and adequate range.

Some commenters expressed concern about the high level of sodium in the children's package. At the time of the preparation of the proposed regulations, it was difficult to interpret these values because although the Food and Nutrition Board had provided some early guidance in the form of the prescribed ranges, the Board had not yet released the accompanying text.

The text, which became available in January 1980, explains the manner in which the values were calculated:(*25*)

> For older infants, children and adults, the lower level of the suggested sodium intake is based on the average intake of a breast-fed 6 months old infant . . . corrected for body size (surface area). At each age the upper level of sodium suggested is three times the lower level.

The FNB also relied on clinical studies that have been done to make determinations about the sodium requirements for adults. The FNB has indicated that there are few data on which to base the ranges. This is particularly true for children. The children's ranges have therefore been based on values interpolated from studies involving adults and infants.

[b] Sodium content of high sodium package calculated on the basis of maximum amounts of American cheese, which has the highest sodium content of all authorized cheeses, and peanut butter.

The Department believes that it is particularly important to be cautious about the interpretation of the ranges set for safe and adequate intakes for children. The comparison of all of the food packages to the ranges indicates that the maximum sodium content of each of the packages, except the children's package, is at the mid-portion of each range. This is appropriate because the safe and adequate levels set by the Food and Nutrition Board are suggested intakes for a day and not simply sodium limits for supplementary foods. Given that other foods will be consumed by participants, the total sodium intake of an individual should not be supplied by the WIC foods.Yet, calculations show that the supplemental foods in the children's package could provide over one and one-half times the amount of sodium that the Food and Nutrition Board suggests children should consume daily. There is a great discrepancy between the way in which the sodium contents of the packages for children and adults compare to the suggested standards for sodium even though similar foods are provided to children and to adult participants. The fact that the sodium value is high for the children's package relative to the values for the adult packages can be partially explained by examining the caloric content of the packages as well; the children's package provides a greater proportion of the calories that children need each day than do the packages for pregnant, breastfeeding and post partum women. Therefore, it is expected that a greater proportion of sodium will be provided for children. However, this still does not explain the fact that the children's values are so high relative to the FNB ranges while the adult values are not.

A similar discrepancy is apparent when nationwide food consumption data are examined. Food consumption data from the Health and Nutrition Examination Survey (HANES) were analyzed for sodium content.(*26*) The data cover only naturally occurring sodium in foods and sodium added by processors. Table salt is not incuded in these data. The data analyses show that the mean daily sodium intake of women 12 to 17 years of age was 1977 mg. Women 18 to 44 years of age had a mean intake of 1838 mg. The values fall well within the range suggested by the Food and Nutrition Board for women of childbearing age. By contrast, the HANES data show that children 1 to 5 years of age have a mean daily sodium intake of 1785 mg. This value exceeds the ranges recommended by the Food and Nutrition Board despite the fact that

added tables salt is not included in the calculations.

A survey conducted by the Food and Drug Administration (FDA) also provides some information about the dietary intake of sodium.(*27*) In 1976 the FDA analyzed "market baskets" of food items representative of the retail purchase for a 1300 kilocalorie diet for children 2 years of age. Two market basket collections of foods contained 1928 and 1759 mg. of sodium. These values include naturally occurring sodium and commercially added salt. They do not include salt added at home. Still, the values are well above the FNBV suggested range.

There are many reports that indicate that Americans consume much more sodium then they need. The Food and Nutrition Board reports,

> The average sodium chloride intake in this country is about 10 grams per day, with a range of 4–25 grams. This average intake is 20 times the nutritional requirement.(*28*)

Clearly, a significant reduction in the amount of sodium consumed would require certain changes in the eating habits of Americans. The FNB states, "In practice, for the average adult the estimated safe and adequate intakes suggest a reduction in usual sodium intake by half . . ."(*29*) Adherence to the sodium levels suggested by the FNB would require even more significant changes in children's eating habits.

Dietary sodium occurs naturally in foods or it can be added to foods as salt either at home or in commercial food processing. Cheese, milk, and shellfish are common natural sources of sodium in the diet. Meat, fish, poultry and eggs also contain a significant amount of sodium.(*30*) The addition of salt to foods at home is termed discretionary use of salt. Discretionary use accounts for approximately one-third of the total amount of sodium consumed by adults. In the average diet, salt added in commercial food processing contributes a slightly larger proportion of dietary sodium.(*31*) Salt is added to a variety of processed food products. It is added to dairy products such as cheese, which is also a significant natural source of sodium, as well as to cereals which are naturally low in sodium, but may contain significant amounts of sodium after processing.

One reason that the sodium levels appear relatively high, both in the nutrient analysis of the WIC food package for children and in the analysis of food consumption data for children, is that a large proportion of children's calories are supplied by dairy products. The HANES food consumption data were analyzed to determine the amount of sodium that various food groups contribute to the diet.(*32*) The dietary intake values represent sodium that is naturally occurring in foods as well as sodium that is added in food processing. The discretionary use of salt is not reported. In the HANES analysis, grain products contributed the most sodium, providing an average of 20 percent. The milk and milk products group was the second major source of sodium intake; it provided an average of 14 percent. However, children one to five years of age showed a higher percent of sodium intake from milk and milk products (19 percent) than any other age group did. This pattern is expected because of the higher consumption of milk and milk products by the younger age groups.

The products in the food packages do provide sodium in the diet, but they also provide essential nutrients that are needed by WIC participants and particularly by children. In order to conform to the range for sodium in children's diets suggested by the Food and Nutrition Board, it would be necessary to make some major changes in the types of products offered in the package. For example, cheese generally has a higher sodium content than milk does. Even if the substitution of cheese for milk were not permitted in the children's package, the sodium level for the children's package (910 mg.) would still approach the upper level established by the FNB for young children. This would necessitate some reduction in the amount of dairy products or other products which are significant sources of sodium, such as cereal or peanut butter, in the package. The Department believes that such changes might result in the sacrifice of needed calories and nutrients. One commenter suggested that the high contribution of complete protein and calcium compensates for the high sodium content of milk and cheese.

In view of the fact that there are few data on which to base recommended ranges for sodium intake for children and the fact that conformance to the ranges suggested by the Food and Nutrition Board would necessitate major revisions in the dietary practices of children, the Department believes that it is not appropriate at this time to apply the FNB ranges as a strict standard. However, the ranges do provide some guidance and the Department believes that it is appropriate to be concerned about the amount of sodium in the food packages. The sodium levels in the food packages are not consistent with the recommendations in the scientific literature to reduce the consumption of salt.

One change made in these rules, while its primary purpose is to control the cost of the WIC food package (see section of the preamble on cheese) will also reduce the sodium content of the package. A 4 pound limit will be placed on the amount of cheese that can be substituted for milk in the WIC food packages.[c] (The regulations specify that cheese may be substituted for milk at the rate of one pound of cheese per 3 quarts of milk.) This new limit will not reduce the amount of dairy products that are provided in the package; it simply provides that no more than about half of the milk in the package can be replaced with cheese. This will reduce the maximum sodium content of the packages by approximately 30 percent. The highest possible sodium contents of the food packages which contain a maximum amount of 4 pounds of cheese will be approximately 1645 mg. for pregnant and breastfeeding women, 1480 mg. for post partum women, and 1580 mg. for children. It is important to note that these figures represent the highest possible sodium content of each food package. If a participant chooses beans instead of peanut butter the sodium level in the package would be further reduced.

The sodium content of the package could also be reduced if participants chose certain cheeses with lower sodium contents rather than those higher in sodium. The sodium levels in cheeses that are available to WIC participants vary considerably. The following table illustrates the range of values:

Amount of Sodium per Ounce of Cheese Available to WIC Participants

Types of cheese	Sodium content (mg. per ounce)
Natural Swiss	74
Mozzarella (whole)	105
Mozzarella (skim)	132
Monterey Jack	152
Brick	159
Colby	171
Natural Cheddar	176
Muenster	178
Provolone	248
American	406

It is clear that the sodium content of American cheese is a good deal higher than that of the other cheeses. Some commenters have suggested that American cheese, or other processed cheeses, should not be made available to participants for this reason. One commenter pointed out that while the high quality protein and calcium in milk

[c] For individuals determined by the competent professional authority to be lactose intolerant, a larger quantity of cheese can be prescribed.

and natural cheese justify their inclusion in the package, processed cheese, which has such a high sodium level, has no additional attributes that natural cheeses lack.

The report prepared by a DHEW task force on disease prevention and health promotion makes similar recommendations.(*33*) The task force suggests that in order to reduce animal fat, refined carbohydrates and salt in the diet, negotiations with the food industry should be undertaken to reduce the sugar content of foods, especially foods for children, such as breakfast cereals; to reduce animal fat content in processed foods; and to reduce the salt that is added when foods are processed.

The inclusion of such a high sodium food product in the packages has also been discussed in terms of the influence that it may have on nutrition education efforts. There is some concern that participants may be confused if they are advised to moderate their sodium intakes, but at the same time, products that contain large amounts of sodium are made available.

Some advantages of providing American cheese in the food packages were also discussed by those who commented on the list of cheeses that were proposed for inclusion in the packages. Commenters pointed out that American cheese is generally less expensive than the other cheeses that are allowed. Also, some commenters stated that American cheese is a more popular cheese, particularly among children, than the other alternatives provided. They believe that it is important to provide a product in the package that is appealing because participants will not benefit from the nutrients in the cheese if they do not consume it.

Although the Department did not specifically ask for comments on the exclusion of high sodium cheeses from the food packages, some people did discuss the issue. It is obvious from the comments not only that the issue is an important one, but also that it is a very complicated one. The Department wishes to gather additional information on the subject and to provide an opportunity for persons to comment on whether the Department should propose that high sodium cheeses be removed from the food package. Therefore, the second action that the Department is taking in relation to the sodium content of the food package is to request comments on the issue of the exclusion of high sodium cheeses from the food packages. If the Department subsequently decides to pursue regulatory action in this area, a new proposed rule will be issued. The Department is particularly interested in receiving comments that discuss the administrative consequences of such a regulatory change, that provide an indication of the acceptability, availability and cost of types of cheeses on the market, and that discuss standards for sodium content that might be applied in such a rule. Those persons interested in commenting on this issue should submit their comments to the address listed in the first part of the preamble within 60 days of the publication date of this final rule.

Fat

The amount and type of fat in the diet of the general U.S. population is also of concern. The American Society for Clinical Nutrition report (*34*) found a relationship between cholesterol and saturated fat and coronary disease. The Surgeon General's report (*35*) recommends reduction of calories, cholesterol and fat. The 1980 RDA's (*36*) suggest that total fat intake, particularly in diets below 2000 kcal should not contain more than 35 percent of the calories as fat. This suggested level of 35 percent is a standard for the total diet. As with the FNB's safe and adequate levels of sodium, there is also some difficulty in translating the standard of 35 percent of the total calories as fat to assess the appropriateness of the supplemental food packages. The heavy reliance on dairy products in the food packages, some of which contain relatively high levels of fat, is intentional because they are a good source of many of the nutrients shown to be lacking in the diets of the target population and provide needed calories.

The fat content of the WIC food package will vary depending on whether whole or skim mik, cheese and/or peanut butter are included. The lowest fat content will be found in an all skim milk package with beans rather than peanut butter. Conversely the highest amount of fat will be in the package with the maximum amount of cheese (4 pounds) and peanut butter.

The fat content of the food package varies from approximate ranges of 12 [d] to 47 percent [e] for pregnant/breastfeeding women, 11 [d] to 48 percent [e] for the post partum women and 11 [d] to 48 percent [e] for 1 to 5 year olds.

Several commenters indicated the fat content of some of the food packages exceeded the suggested 35 percent of calories from fat. However, there were mixed opinions on how to set a fat level in the food package. Fourteen commenters felt fat should be reduced primarily through nutrition education. One commenter stated that the nutritional value of milk and cheese outweighs their fat content. Only one commenter recommended that fat contribute less than 35 percent of total calories in the WIC food packages.

Although the Department could decrease the fat content of the children's or women's package by eliminating cheese or peanut butter, and/or increasing the use of skim milk, the Department believes that reducing the level of fat for all participants by such a restriction would not be appropriate. Milk products contribute proportionately more fat than most other food groups and these food packages provide less than ¾ of total caloric needs. Given the consumption of other foods containing lesser percentages of fat, the total percent of fat in the diet, which is the real concern, should be less than these stated levels. A range in fat levels in the package is essential because of the varying needs of the population served. A recent study indicates that ⅓ of pregnant women entering WIC were underweight at the time of conception. (*37*) Such women would be in need of a higher fat package to provide necessary calories. Other women in WIC who are obese would need access to lower fat packages. There is also a variance in caloric requirements in preschoolers, with excessively underweight children needing foods dense in calories and high in fat to aid in increasing caloric intake, while overweight children may need access to lower fat foods.

The Department's decision on fat is not inconsistent with its decision on sugar. Although sugar is also a source of calories, sugar, on a per gram basis, contributes only one-half the number of calories as fat does to the diet. In its comments, one food company pointed out that presweetened cereals generally do not contribute more calories than unsweetened cereals, and therefore, the sugar restriction should not affect caloric intake. However, a decrease in the fat content of the food packages could substantially decrease calories. Although some individuals may require a package containing lower amounts of fat, this recommendation cannot be generalized to the majority of women and children participants. A reduction in the fat levels of the food packages will be done on an individual basis by the competent professional authority. For those participants for whom obesity is a

[d] Low-fat package: all skim milk; 2 dozen eggs; beans rather than peanut butter.

[e] High-fat package: whole milk and maximum cheese allotment (Cheddar cheese, which has the highest fat content of all authorized cheeses, was used in determining % fat of the high fat packages); 2½ dozen eggs; peanut butter.

problem, the nutrition education sessions provided in WIC will stress the higher caloric contribution of fat to the diet (9 calories per gram) as compared to protein or carbohydrate (4 calories per gram).

Summary of Fat, Sugar and Salt Issues

The final food package regulations are designed to provide an appropriate content of sugar, salt and fat in the food items. Several of the commenters believed that the decisions in the proposed regulation to limit the sugar content, but not the fat and salt content, of the food packages were inconsistent. However, the Department does not believe this criticism is valid.

Both salt and sugar in the food package have been constrained to acceptable levels for the participant population. The reduction of sugar and salt in the American diet has been a consistent recommendation from the scientific literature. The reduction in sugar and salt will not harm the WIC population and may indeed provide positive benefits. It is with this in mind that a maximum level of sugar in cereals has been set, flavored milk has been deleted and a maximum level of cheese which will have the effect of decreasing sodium has been included in these recommendations.

A similar restriction has not been proposed for fat. Unlike the sugar and salt, expert opinion suggests that a decrease in fat may indeed have adverse effects on the WIC child population. The Department does not find evidence to suggest that a general decrease in fat would enhance the appropriateness of the food packages. The competent professional authority can identify those individuals who because of hyperlipidemias, obesity and other medical conditions need to modify their fat intake.

Food Package Categories. Present WIC regulations specify three food package categories. The proposal expanded this to seven food package categories as follows:

I. Infants 0 to 2–4 Months
II. Infants 2–4 to 6 Months
III. Infants 6 to 12 Months
IV. Children 1 to 5 Years
V. Children 1 to 5 Years with Special Dietary Needs
VI. Pregnant and Breastfeeding Women
VII. Non-Breastfeeding Post partum Women

Of the 316 comments on the proposal to offer seven different food packages, 176 were generally opposed. Those commenters opposed believed the proposed food packages were too restrictive and complex. The 140 supportive of the seven food packages believed the proposed food packages would emphasize the need for tailoring, reinforce nutrition education and prevent waste.

One hundred and twenty-two (122) commenters criticized the three infant food packages, because of the limit placed on the competent professional authority's flexibility to determine the best time for the introduction of infant cereal and juice. In addition, three separate food packages for infants would require frequent food package changes within a short period of time (12 months), resulting in administrative problems because of data processing restrictions and limited staff at some State and local agencies. Therefore, the Department decided to define two infant food packages instead of three in the final regulations—one for infants 0 through 3 months and one for infants 4 through 12 months. The two infant food packages will ensure that infants under 4 months of age do not receive cereal or juice and will allow flexibility for State and local agencies to establish policies and competent professional authorities to use their judgment regarding the introduction of these foods to infants at or after 4 months of age. The age ranges selected for these food packages were those most frequently suggested by commenters. The Department believes these age ranges are the most appropriate in consideration of recommendations for feeding infants and administrative concerns. (Infant feeding recommendations are discussed in the section of this preamble concerning specific foods.)

The Department did not propose any changes in the food package for children with special dietary needs, except for the proposal to allow an additional 52 fluid ounces of concentrated liquid formula or equivalent amounts of powdered or ready-to-feed formula if needed. According to previous regulations, the food package for children with special dietary needs provided for children with conditions that preclude the use of the supplemental foods defined in the package for children 1 to 5 years. This package was designed for children who need formula for an extended period of time.

In the past, the Department has had requests to provide formula to women with lactose intolerance and phenylketonuria (PKU). These formulas were authorized in previous regulations in the food package for children with special dietary needs. Although the Department encourages the use of conventional foods, such as cheese or small quantities of milk, whenever possible in the dietary management of lactose intolerance, the Department realizes that the nutritional demands imposed by pregnancy and lactation, combined with personal food preferences, may make it difficult for some lactose intolerant women to meet their nutritional needs through the use of conventional foods. Even more importantly, the Department is concerned about providing assistance to pregnant women with PKU. An infant of a mother with PKU may be aborted or born damaged, possibly because of the high levels of phenylalanine in the mother's blood. During pregnancy, returning to a diet low in phenylalanine content which requires the use of a special formula may help prevent these problems.(*38*) Therefore, in order to make provisions to allow women to receive formula, the special dietary needs package is authorized for women and children. Physicians must determine and document the reason for issuing this package.

Approximately 80 commenters recommended that the food package for children with special dietary needs contain additional foods when appropriate. The Department considered adding additional foods including eggs and dry beans or peas or peanut butter to the food package for children and women with special dietary needs. Children and women are put on this package because they cannot consume conventional foods and need formula. Some conditions for which the special package may be prescribed, such as PKU, basically preclude the use of eggs, dry beans, peas or peanut butter. Therefore, it would be inappropriate to include eggs, dry beans or peas and peanut butter in the food package for these participants. Other conditions for which the special package may be prescribed, such as lactose intolerance, do not preclude the use of these foods. However, the dietary management of lactose intolerance can frequently be accomplished through modification of conventional diets. The Department believes it is appropriate to encourage using conventional foods in the dietary management of lactose intolerance rather than foster dependence on formulas. A well balanced diet of conventional foods is the most appropriate means of adequate nutrition. Furthermore, formulas are relatively expensive and it may be difficult for participants to purchase formulas after they are terminated from the WIC Program. Therefore, in an effort to discourage the issuance of the food package for children/women with special dietary needs except when the use of formula is absolutely necessary,

the Department has decided not to authorize additional foods including eggs, dry beans or peas and peanut butter in this food package.

Few commenters addressed the issue of a separate food package for children. However, commenters generally supported the specific provisions of the food package for children. Therefore, the food package for children 1 to 5 years of age will remain as proposed. This package was separated from the packages for women in recognition of the fact that children's nutritional needs differ from the nutritional needs of women.

The separate food packages for women were subject to some criticism. Although commenters supported the enhanced food package for pregnant and breastfeeding women, the non-breastfeeding post partum women's food package was criticized by 171 commenters. Concern for the post partum women at nutritional risk, particularly adolescent mothers, was expressed because of an adolescent mother's need to replenish nutrient stores. Commenters opposed to the separate food package for non-breastfeeding post partum women believed a punitive measure was implied. Additionally, they felt different amounts and types of foods for women participants depending on whether they are pregnant or breastfeeding women or non-breastfeeding post partum women would cause confusion and administrative problems.

The Department supports breastfeeding as the preferred means of infant feeding. Although the enhanced food package for pregnant and breastfeeding women may not be a primary factor in a mother's decision to breastfeed, it does provide her some incentive to breastfeed and support to her commitment once the decision is made. Furthermore, the enhanced food package for pregnant and breastfeeding women recognizes that the nutritional needs of these participants are greater than the nutritional needs of non-breastfeeding post partum women.

The Department is aware that adolescents are at greater risk of health problems during pregnancy and are more likely to have poor pregnancy outcomes than are older women. However, many of the reasons adolescents are considered to be at higher risk are related to socioeconomic rather than biological factors. For example, pregnant adolescents are more likely than the general population of pregnant women to be of low socioeconomic status, to have short interpregnancy intervals and to have less access to prenatal care. (*39*)–(*40*) Since many of the women enrolled in WIC have some of these characteristics, providing the post partum adolescent with an enhanced food package over that of other post partum women is not justifiable.

In comparing the requirements of post partum adolescents to pregnant and breastfeeding women, it is evident that the requirements for most nutrients are substantially greater for the latter group. The enhanced food package for pregnant and breastfeeding women is meant to address those added requirements. The requirements for post partum adolescents and post partum adult women do not differ as much as those of post partum women versus pregnant and breastfeeding women.

The priority system for access to WIC states that pregnant or breastfeeding women should be enrolled in WIC prior to postpartum women of any age. This system was set up because of the increased nutritional needs of the former group. In line with the reasoning behind this priority system, it is appropriate that pregnant and breastfeeding women be given an enhanced food package over postpartum women including adolescents. Additionally, because of the limited funds available, the Department believes that is is necessary to ensure that the participants with the greatest needs who may benefit most by consuming the supplemental foods receive the greatest quantity and variety of foods.

The final food package catagories are defined as follows:

I. Infants 0 through 3 Months
II. Infants 4 through 12 Months
III. Children/Women with Special Dietary Needs
IV. Children 1–5 Years
V. Pregnant and Breastfeeding Women
VI. Non-Breastfeeding Postpartum Women

These package categories are designed to ensure that the types and amounts of food provided to participants more accurately reflect infants' nutritional and development needs, current pediatric feeding recommendations, and the nutritional requirements of pregnant and breastfeeding women. The Department has decided six separate food packages are necessary, because there is little evidence of individual food package tailoring. The 1979 GAO report and management evaluations revealed that tailoring was not a common practice. Specifically, the GAO report stated that "With a few exceptions, the local programs were making little or no attempt to prescribe individual food packages. Instead, the maximum allowable standard quantities of all foods were given to nearly all participants. (*41*) Given the lack of tailoring, these six food packages respond to criticism that the current three food packages may provide too much food in relation to the nutritional needs of certain categories of participants.

The Department will continue to require the competent professional authority at the local agency to tailor food packages on an individual basis taking into consideration the participant's age and dietary needs. It is most important that the types and quantities of food provided be appropriate for the participant. Examples of tailoring include determining the best time, after 3 months, to issue cereal and juice to infants based on individual growth and developmental needs; and determining the types and amounts of food a participant with special dietary needs should receive. In the case of breastfed infants, if supplemental feedings of infant formula are necessary or desired, infants may receive appropriate quantities of infant formula. The Department believes that the six food packages specified in this regulation will serve as a foundation for further tailoring, prevent waste and reinforce nutrition education.

Maximum Quantities

Policy in the area of tailoring the food package to meet an individual's nutritional needs has been continuously issued since the initiation of the WIC Program. The Department approves the tailoring of an individual's food package at the local level to meet an individual's specific needs. However, the Department would like to reinforce and clarify its policy on maximum food quantities. The Department believes that while State agencies have wide discretion concerning the foods provided under the WIC Program, the Department cannot allow a Statewide categorical limitation set by a State agency on the quantity of a specific food. Thus, the State agency cannot specify a maximum quantity, on a Statewide basis, for all participants, that is less than the maximum quantity set forth in this regulation. This does not mean that every participant must receive the maximum quantities of all foods as set forth in the regulations. It does that the maximum quantities must be available to all participants, if needed. It also allows the competent professional authority the flexibility to prescribe specific food quantities based on an individual's particular nutritional needs.

Foods

Formula—Iron Fortification. Commenters were almost evenly divided on the issue of whether to allow non-iron-fortified formula under special circumstances. Of 619 comments, a slight majority, 54 majority, supported allowing non-iron-fortified formula. Further analysis of the comments on this subject revealed that both the medical and nutrition communities had mixed opinions. Almost equal numbers of physicians, nurses and nutritionists supported and opposed allowing non-iron-fortified formula. Many commenters believed some infants need non-iron-fortified formula and the WIC Program should meet these individual needs. Conversely, many commenters opposed to the allowance of non-iron-fortified formula pointed out that no scientific evidence exists to prove true incidence of intolerance to iron and the provision of non-iron-fortified formula defeats the purpose of the Program. Also, commenters indicated that allowing non-iron-fortified formula would be inconsistent with recommendation of the American Academy of Pediatrics.

The Committee on Nutrition of the American Academy of Pediatrics recommends that either breast milk or iron-fortified formula be fed to healthy infants from birth to 12 months of age.(*42*) Iron deficiency is the most common cause of anemia in infants. Surveys of infants and children indicate that the highest incidence of anemia is found among lower socioeconomic groups. The risk of iron deficiency is greatest after iron stores built up in utero have been depleted. This occurs after about two months in small preterm infants and after four to six months in term infants. "Animal studies indicate that iron deficiency anemia early in postnatal development results in some abnormalities that persist long after the anemia itself has been corrected. Therefore, it appears important to keep the iron intake of infants at a high level to prevent anemia and other clinical manifestations of iron deficiency."(*43*)

The authorization of non-iron-fortified formula for all infants would decrease the iron content of the infant food packages considerably. The iron content of the food package for infants 0 through 3 months would be reduced from approximately 9.4 mg. of iron per day to trace amounts of iron. The iron content of the food package for infants 4 through 12 months would be reduced from approximately 26.3 mg. of iron per day to approximately 16.9 mg. of iron per day. The major source of iron in the food package for infants 4 through 12 months of age, other than iron fortified formula, is infant cereal. In its comments to the proposed food package regulations, the Committee on Nutrition of the American Academy of Pediatrics stated that "it is unlikely that iron-fortified cereal can be relied on to prevent iron deficiency in infants 6–12 months of age who are fed cow's milk."(*44*) Since the iron content of non-iron-fortified formula is about comparable to the iron content of cow's milk, the Department believes this statement is applicable to the decision on authorizing non-iron-fortified formula for healthy infants.

Intolerance to iron-fortified infant formula is a controversial issue. Although some physicians are opposed to the use of iron-fortified formula because of the belief that it causes fussiness, colic, spitting up, diarrhea or constipation, other physicians use iron-fortified formula regularly and consider such manifestations uncommon.(*45*) A recent study supports the view that these problems are not related to the iron in the formula. In this study infants fed iron-fortified formula were compared to similar infants fed non-iron formula from the 3rd day of life for a period of 42 days. A review of daily records kept by the mothers revealed no differences in the number of stools per day, the description of the stools, the number of days without stools, or the incidence or frequency of colic, spitting up, or vomiting.(*46*)

The Department has concluded that available information does not substantiate the authorization of non-iron-fortified formula for healthy infants. Therefore, for healthy infants, only iron-fortified formula is authorized in the final regulations. A small number of infants have medical conditions which necessitate restricting iron intake or using a specific formula which does not meet the iron requirement for formula. In order to meet the needs of these infants, as well as healthy infants, the Department has decided to authorize the provision of non-iron-fortified formula when medically necessary. The authorization of non-iron-fortified formula is discussed under the section of this preamble dealing with special formulas.

Formula—Calorie Requirement. Although the Department did not propose any changes in calorie requirements for formulas, 56 commenters recommended that low-calorie formula no longer be authorized for issuance. They believed that nutrition education is a more effective way to deal with weight management. In consideration of these comments and nutrition education principles, the Department has decided not to authorize low-calorie formula for infants, children and women for the purpose of managing body weight.

Low-calorie formula has been issued in the past primarily to overweight infants, 6 to 12 months of age, and overweight children. The use of low-calorie formula for this purpose appears inconsistent with suggested feeding practices. The American Academy of Pediatrics indicates that there is no evidence that use of skimmed or partially skimmed milk in the absence of other dietary measures results in a decrease in the total caloric intake of children who usually make up the missing calories from other sources. When foods other than milk are introduced, it is suggested that the quantity of milk or formula that is consumed be decreased.(*47*) In addition, the feeding of milk of reduced fat content is not recommended during infancy.(*48*) Forty-three State agencies already restrict the use of low-calorie formula in the infant food package. The Department believes that the preferred strategy for dealing with problems of over-nutrition in infancy and childhood is through a varied and well-balanced diet rather than the use of low-calorie formulas.

Formula—Substitution of Whole Milk—Previously, whole milk could be substituted for formula in the infant food package beginning at 6 months of age. Although the Department did not propose any changes in the substitution of whole milk for formula, 123 comments were received on this provision of the regulations. Fifty-six percent of these commenters were opposed to authorizing the substitution of whole milk for formula in the infant food package beginning at 6 months of age. These commenters stated that feeding infants whole milk at 6 months is not medically sound, is against recommendations of the American Academy of Pediatrics and not consistent with the goals of the WIC Program.

As stated previously, the Committee on Nutrition of the American Academy of Pediatrics recommends that either breastmilk or iron-fortified infant formula be fed to healthy infants from birth to 12 months of age. In reference to the feeding of milk to infants, the Committee further states that "unmodified cow's milk and evaporated milk at usual dilutions do not meet the proposed standards (for infant formulas). Although normal growth occurs with the use of cow's milk, iron deficiency and hyperphosphatemia are common complications. Vitamin C supplements are needed. The high salt

and saturated fat content of cow's milk may have adverse effects on later health, although this has not yet been proven. Its high protein and mineral content increase the risk of dehydration and hypernatremia(*49*) whenever diarrhea or other conditions increase the demand for water."

The WIC Program is principally aimed at preventing the development of nutrition/health problems in a high risk population. The Department believes that because the feeding of whole milk to infants may have both immediate and long term health consequences for the individual, the authorization of whole milk in the infant food packages is inappropriate. Therefore, the Department is completely deleting the authorization of whole milk in the food packages for infants.

Formula—Special Formulas—Previously, the Department required that all formulas provided to infants and children with special dietary needs meet the requirements for formula intended for use by infants as defined in the regulations. This definition included a calorie and iron requirement and required that the formula be a complete formula. An exception clause was not included in the regulations to allow the provision of formulas which did not meet these requirements when medically necessary.

Some formulas available on the commercial market for the treatment of medical conditions which may necessitate the use of a special formula, such as some metabolic disorders, inborn errors of amino acid metabolism, gastrointestinal disorders, malabsorption syndromes, and certain allergies, fulfilled the requirements for formulas as defined in the regulations and were authorized for use in the WIC Program. Other formulas available on the commercial market for the treatment of these types of medical conditions did not meet the requirements for formulas as defined in the regulations and were not authorized for use in the WIC Program. For example, although a formula designed for use by infants and children sensitive to intact protein of milk and other foods was authorized, a formula designed for use by infants with celiac disease was not authorized. The Department has received a number of requests to expand the definition of formulas authorized for use by infants and children with special dietary needs to allow additional types of formulas when needed.

Participants with medical conditions that necessitate the use of a special formula have very individualized needs. The Department believes that the physician caring for these participants is the most appropriate person to determine the specific formula which the participant should receive. As an adjunct to health care, the WIC Program should provide the best available formula to the participant, as determined by the physician. WIC Program regulations should have sufficient flexibility to accomplish this with a minimal burden being placed on physicians and administrators. Therefore, requirements for formulas authorized for use in the WIC Program are modified to allow the provision of formulas used in the treatment of medical conditions which were not previously authorized. Because formula is provided to all infants under one year of age who are not breastfed but is provided to older children and to women only if they have medical conditions which necessitate the use of formula, the manner by which special formulas are authorized in the infant food packages and the food package for children/women with special dietary needs is different. This is intended to minimize the burdens placed on physicians and administrators.

The Department believes that the vast majority of infants who are not breastfed should be fed formulas which meet the requirements for formula as previously defined. This definition has sufficient flexibility to allow both milk base and soy base formulas. Therefore, for healthy infants and lactose intolerant infants who do not have other medical conditions which prohibit the use of formula as previously defined, the requirements for formulas authorized for use in the WIC Program are maintained. For the small number of infants with medical conditions including, but not limited to, medical conditions which contraindicate the use of iron-fortified formulas, metabolic disorders, inborn errors of amino acid metabolism, gastrointestinal disorders, malabsorption syndromes and allergies, formulas which do not meet the requirements for formulas otherwise authorized, are authorized when the physician caring for the infant determines the need for the formula. Documentation of the physician's determination and the specific formula prescribed must be included in the participant's certification file. For the reasons stated under the section of this preamble concerned with calorie requirements for formulas, infants may not receive low calorie formulas solely for the purpose of managing body weight.

In the past, the Department has required that formulas provided to older children with special dietary needs meet the requirements of formulas provided to infants in the infant food package. However, the Department believes that it would be inappropriate to maintain this requirement. The revised requirements for formulas authorized for infants allow the provision of formulas which do not meet the requirements defined in the regulations when a physician determines and documents that it is medically necessary, as described in the preceding paragraph. The food package for children/women with special dietary needs is authorized *only* when a physician determines that the participant has a medical condition which precludes or restricts the use of conventional foods and necessitates the use of a formula. The Department believes that defining requirements for formulas provided to children and women with special dietary needs, but allowing exceptions when the physician determines and documents the need, would result in undue confusion and an unnecessary burden being placed on both physicians and program administrators. Therefore, formulas authorized under the food package for women and children with special dietary needs are redefined according to conditions rather than formula composition.

Formulas are authorized for children and women under this regulation in the food package for children/women with special dietary needs when a physician determines and documents that the participant has a medical condition which precludes or restricts the use of conventional foods *and* necessitates the use of a formula including, but not limited to, metabolic disorders, inborn errors of amino acid metabolism, gastrointestinal disorders, malabsorption syndromes, and allergies. The physician's determination and the specific formula prescribed by the physician for the management of the participant's condition shall be documented in the participant's certification file. As stated previously, lactose intolerant infants are not considered to require a special formula because soy formulas are authorized under the definition of formula in the infant food packages. However, since there is no definition of formula, per se, in the food package for children/women with special dietary needs, lactose intolerant children and women may receive soy formula, if needed, in the food package for children/women with special dietary needs. Because the Department believes that the best source of adequate nutrition is a well balanced diet of conventional foods and nutrition education is provided to

participants to assist them in meeting their nutritional needs, children and women are not authorized to receive formulas solely for the purpose of enhancing nutrient intake. Additionally, because the Department believes the management of body weight should be approached through modifications in dietary habits rather than reliance on formulas, as described in the section of this preamble on caloric requirements for formulas, children and women are not authorized to receive formula solely for the purpose of managing body weight.

Some commenters expressed concern about the requirement that the physician's determination that non-iron-fortified formula is necessary for the medical management of an infant be documented in the participant's file. These commenters believed that the requirement would present administrative problems. The Department realizes that some additional administrative tasks will occur as a result of the documentation requirements for special formulas. However, because special formulas will be issued to participants rarely, the Department believes the administrative burden will be minimal.

Formula—Additional Quantities. The Department proposed allowing an additional 52 fluid ounces of concentrated liquid formula or equivalent amounts of powdered or ready-to-feed formula for infants and for children with special dietary needs when a physician determines and documents the need for the additional formula. Two hundred and eighty-three (283) commenters generally supported the provision of additional formula, primarily because larger infants may need extra formula and whole milk may be substituted after the month's supply of formula is consumed. Also, infants and children with special dietary needs may need to consume greater quantities of formula than the basic amount authorized and special therapeutic formulas are very expensive. One hundred and thirty-eight (138) commenters objected to adding more formula, particularly in the infants' packages. Their objections were based on the fact that WIC is a supplemental food program; and any extra formula if, in fact, it is necessary should not be supplied by the WIC Program. Also, commenters were concerned about the cost of the additional formula and the possibility of encouraging overfeeding.

In an attempt to contain the cost of the food packages and maintain the supplemental nature of the WIC Program, the Department has decided not to allow the provision of additional formula in the food packages for infants. An additional 52 fluid ounces of concentrated liquid formula or equivalent amounts of powdered or ready-to-feed formula would substantially increase the cost of the infant food packages. Based on prices in the Washington, D.C., metropolitan area in the Spring of 1980, authorizing an additional 52 fluid ounces of concentrated liquid formula would add approximately $3.00 to the cost of the infant food packages. Although every infant on the Program would not receive the additional formula, given the percent of infant participants (approximately 25 percent of all participants), if a large number of infant participants were to receive the additional formula, the increase in cost of this package would eventually result in fewer participants being served.

To better meet the needs of children/women with special dietary needs who may consume greater quantities of formula than previously authorized, the Department is allowing the provision of an additional 52 fluid ounces of concentrated liquid formula or equivalent amounts of powdered or ready-to-feed formula in the food package for children/women with special dietary needs when a physician determines and documents the need. The additional formula for children/women with special dietary needs will be beneficial to participants, since special therapeutic formulas are particularly expensive. Although the cost of the food package will be increased, the number of participants receiving this food package is small. Data from State agencies indicate that approximately 2.6 percent of children receive the food package for children with special dietary needs. Therefore, the impact on overall food package costs will be minimal. To prevent abuse, the competent professional authority shall document the need for the additional formula in the food package for children/women with special dietary needs.

Infant Cereal. Approximately 636 comments were received on the delayed introduction of cereal in the infant food packages. Three hundred and eighty-four (384) comments supported the delayed introduction of cereal in the infant food packages until 2–4 months. Two hundred and fifty-two (252) opposed the delayed introduction of cereal at 2–4 months. Of those opposing, most were critical of the age range; 195 commenters recommended a different age for the introduction of cereal. Many commenters believed that 2 months of age was too early to introduce cereal; the most frequently recommended age was 4 months.

Guidelines on the feeding of solid foods to infants developed by the American Academy of Pediatrics include the recommendation that foods other than breastmilk or infant formula be introduced into the infant's diet when the infant weighs 6 to 7 kilograms and is at least 3 months of age. *(50)* The 50th percentile weight for age is 6 to 7 kilograms for boys between approximately 3 and 4 months of age and for girls between approximately 4 and 5 months of age. *(51)* By 4 months of age, most infants are physically and developmentally ready to begin solid foods. *(52).*

Infant cereal is usually the first solid food introduced into the infant's diet. Therefore, the Department has decided to allow the issuance of infant cereal in the infant food package beginning at 4 months of age. The competent professional authority has the option to further delay the introduction of cereal as appropriate for the nutritional needs and developmental readiness of the infant.

In the proposed regulations, the Department proposed to maintain the current requirement that only infant cereals be provided in the infant food package. One hundred and six (106) commenters believed adult cereal should be allowed for older infants mainly because older infants prefer the texture of adult cereals and often refuse infant cereals. However, almost twice as many commenters (195), believed that only infant cereal should be allowed in the infant food packages. Those supporting the provision of only infant cereal to infants stated that infant cereal was more nutritious for infants. The iron compound used to fortify infant cereals is electrolytically reduced iron of small particle size and is, therefore, highly available. *(53)* The iron compound in adult cereals varies; *(54)* thus, the bioavailability of the iron in adult cereals varies. In order to maintain an infant food package providing optimal sources of specified nutrients, the Department will continue to authorize only infant cereal in the food package for infants.

Clarification on the Department's policy concerning prepackaged cereal/fruit and cereal/formula combination items was requested by 22 commenters. These cereal combinations were not allowed under previous regulations and are not allowed under this regulation. The Department's policy is based on recommendations of the American Academy of Pediatrics and cost concerns. The American Academy of

Pediatrics recommends that single ingredient foods be introduced one at a time in an effort to isolate food sensitivities and possibly avert the development of food intolerances. *(55)* Although cereal/fruit combinations may be appropriate once the risk of food sensitivity has diminished, these combination foods are more expensive than regular infant cereal. Therefore, in an effort to contain the cost of the food packages, the Department has not authorized them. In reference to cereal/formula combinations, since infant formula is already provided in the food packages, the Department does not believe it is necessary to provide additional infant formula in combination with infant cereal.

Forty-two (42) commenters requested clarification on the provision of infant cereal to children 1–5 years. Thirty-three (33) pointed out that infant cereal is recommended up to 18 months of age. The requirements for cereals provided to women and children are not intended to preclude the provision of infant cereals to women and children. Any infant cereal which meets the requirements for cereals provided to women and children is authorized for these participants, except as for infants, cereal/formula and cereal/fruit combinations are not authorized for women and children.

Juice to Infants. The Department proposed to delay the issuance of juice in the infant food package until 6 months of age because of a joint recommendation by the American Academy of Pediatrics and the American Academy of Pedodontics which discourages the feeding of juice from a bottle rather than a cup to prevent "bottle caries," a condition resulting from frequent provision of sugar-containing beverages in bottles to infants and children leading to the development of often serve caries. (*56*) Two hundred and twenty-four (224) comments approved delaying juice in the food packages until 6 months. One hundred and sixty (160) opposed the proposal. The Department continues to support recommendations that juice not be given from a bottle. However, the final regulations will allow juice in the food package for infants beginning at 4 months instead of 6 months of age. This change from the proposal was made in view of the comments received criticizing the specification of three separate infant food packages. (See section on Food Package Categories). Although a majority of comments on the introduction of juice supported delaying juice until 6 months, many commenters opposed the three infant food packages, stating that they presented administrative problems. The two infant food packages were defined to help prevent administrative problems and provide some flexibility. Allowing juice starting at 4 months will afford flexibility to State and local agencies to deal with their own systems, and the competent professional authority to make individual determinations. The Department discourages the issuance of juice until the infant can drink from a cup in an effort to discourage mothers from feeding infants juice from a bottle. Since the feeding of juice from a bottle may cause "bottle caries," the competent professional authority shall instruct the participant's parent or guardian to feed the juice to the infant from a cup.

The Department proposed that only adult juice be provided to infants and exceptions to issue infant juice be allowed only when the compentent professional authority documented the need. Opposition to the restriction of infant juice was substantial. Of 423 comments, 277 opposed authorizing only adult juice, while 146 supported the proposal. Commenters noted several problems with the packaging of adult juices. Primarily, the adult juice containers are large. Once the containers are opened nutrients are lost, and the large portions available may lead to overfeeding. The lead content of the juice cans was also a point of concern. Additionally, commenters were concerned that other members of the household may consume the adult juices, leaving an insufficient quantity for the infants.

By restricting the issuance of infant juice, the Department intended to minimize the cost of the infant food package and reinforce the recommendation that juice be fed from a cup rather than a bottle. However, because of the problems cited by commenters, the Department is not placing restrictions on the issuance of infant juice in the food package for infants 4 through 12 months of age. The competent professional authority may continue to issue adult juice, when appropriate, with proper instructions to the participant's parent or guardian on storage and feeding.

Milk—Reduction in Quantities. The Department proposed to reduce the maximum amount of milk authorized for children from 28 quarts to 24 quarts per month. A reduction in the amount of milk was proposed to conform with the American Academy of Pediatrics' recommendation that milk intake should be limited to 720 ml. per day (three 8-ounce glasses) when the intake of solid foods is well established. (*57*) If a major portion of a child's caloric needs is provided from a single food source, such as milk, other foods including those rich in iron may be excluded from the diet. Of 324 comments, 252 agreed with the Department's proposed reduction and thought that 28 quarts of milk per month is not necessary for children. Therefore, the amount of milk authorized for children is reduced to 24 quarts per month. This reduction will still provide slightly more than three glasses of milk per day for those children who may need it.

The Department also proposed reducing the maximum amount of milk for non-breastfeeding postpartum women from 28 quarts to 24 quarts of milk. Of the 337 comments on this proposal, 217 approved of this reduction stating that non-breastfeeding postpartum women do not need as much milk as pregnant and breastfeeding women. Some commenters expressed concern for the non-breastfeeding postpartum adolescent. However, the needs of a pregnant woman or a breastfeeding woman are greater than a non-breastfeeding postpartum adolescent. (The nutritional needs of postpartum adolescents and the Department's philosophy about this issue are discussed in the section on food package categories.) By providing more milk to pregnant and breastfeeding participants, the Department can address the increased nutritional needs of these women. The Department has set a maximum quantity of 24 quarts of fluid milk for non-breastfeeding postpartum women. Pregnant and breastfeeding women can still receive a maximum quantity of 28 quarts of fluid milk.

Milk—Flavored Milk. In the previous regulations, women and children were allowed to receive flavored or unflavored milk. No change in this provision was proposed by the Department. However, 78 commenters requested the deletion of flavored milk from the food packages since flavored milk has a higher sugar content than unflavored milk. They indicated that providing flavored milk contradicts nutrition education and the Department's proposal to limit sugar in the food packages. Furthermore, flavored milk is more expensive than unflavored milk. The Department agrees with these concerns. There are significant differences in the sugar content of fluid whole milk and low fat chocolate milk. Fluid whole milk supplies 12.0 grams of carbohydrate per cup compared to 27.3 grams of carbohydrate per cup provided by low fat chocolate milk. If we assume that the major portion of carbohydrate in milk is

in the form of simple sugar, fluid whole milk contains 4.9% sugar contrasted with 10.9% sugar in low fat chocolate milk. Therefore, to reinforce nutrition education, for consistency with the Department's philosophy about sugar in the food packages, and to maintain food package costs at economical levels, the Department is deleting flavored milk from the food packages for women and children. Although the deletion of flavored milk was not proposed, the comments and the Department's policy on sugar validate this change.

Milk—Goat Milk. In the preamble to the proposed food package regulations, the Department requested comments on the need for goat milk, its availability and whether or not it is pasteurized or fortified with vitamin D. Approximately 397 commenters addressed this issue; 284 opposed allowing goat milk because of its questionable nutritional value. Much of the commercially available goat milk is not pasteurized, and goat milk is usually not fortified with vitamin D. Additionally, goat milk is a relatively poor source of folacin. Commenters also felt that soy formulas are a satisfactory alternative for those participants who cannot tolerate cow milk. Since a number of formulas for participants with special dietary needs are available, the pasteurization and fortification requirements for milk will not be changed to allow for goat milk.

Cheese — Variety. In the previous food package regulations, the domestic cheeses allowed were processed American, Monterey Jack, Colby, natural Cheddar and Swiss. In response to participant requests for additional cheeses to be provided in the food packages, the Department proposed adding Brick, Edam, Gouda, Muenster, Provolone and Mozzarella, part-skim or whole, to the list of allowable cheeses. Out of approximately 410 commenters addressing this issue, 250 supported the inclusion of additional cheeses in the food packages for women and children. The most popular reasons for support cited by the commenters were the added variety in the cheese selection and the allowance of a more versatile food package recognizing geographic and cultural preferences. However, commenters opposing the additional cheeses cited cost and packaging considerations. They said certain cheeses were very expensive and, therefore, inappropriate for low-income persons learning how to purchase foods on a limited budget. Edam and Gouda are in this category, costing approximately $.80 more a pound than the next most expensive cheese listed. In addition, these cheeses come packaged in odd sizes which could make issuance difficult. Therefore, the Department is authorizing processed American, Monterey Jack, Colby, natural Cheddar, Swiss, Brick, Muenster, Provolone and Mozzarella, part-skim or whole, but is not authorizing Edam and Gouda in the food packages for women and children.

Cheese—Quantity. Cheese may be substituted for milk at the rate of one (1) pound of cheese per three (3) quarts of milk in the food packages for women and children. Under the previous regulations, participants could substitute all of the milk portion of their food package with cheese. A total of nine (9) pounds of cheese could be issued in this package. Some State agencies have had policies on the maximum amount of cheese allowed. Five State agencies requested in their comments that a maximum amount of cheese be specified. Although cheese is equivalent nutritionally to milk at the substitution rate of one pound of cheese per three quarts of milk, the costs are not equivalent. One pound of cheese, depending on the type purchased, may cost from approximately $2.09 to approximately $2.79; three quarts of milk cost approximately $1.41. When the milk portion is totally replaced with cheese, the costs of the food packages increase substantially.

In an attempt to contain the costs of the food packages the Department has decided to set a limit on the amount of cheese that can be substituted for milk. Under these regulations, four pounds of cheese is the maximum amount that may be substituted for milk. This will allow participants to replace about half of the milk with cheese. Given concerns over the cost of the package, and the waiting lists of both clinics and participants who cannot currently be served by the Program due to funding limitations, the Department did not feel it could allow for more than half the milk in the food package to be replaced with cheese. Since the WIC Program is a supplemental program and is not intended to provide an entire diet, this amount is considered sufficient.

An exception is made for persons with lactose intolerance. In cases of lactose intolerance, the competent medical professional may issue additional amounts of cheese.

Additionally, some commenters suggested that if the Department restricted the amount of cheese that can be substituted for milk, the sodium content of the food packages could be reduced. Limiting the amount of cheese that can replace milk to four pounds per month (or about one pound per week per WIC participant) also accomplishes this goal. The section of the preamble concerning salt, sugar, and fat provides more information on this matter.

Eggs. The provision of two and one-half dozen eggs under the previous food package regulations has caused problems for many local agencies and participants, primarily due to problems with purchasing one-half dozen eggs. Many grocery stores have policies prohibiting the splitting of egg cartons, or they do not sell eggs in one-half dozen amounts. Information from State agencies indicates that 49 have problems splitting cartons. To alleviate this problem, the Department has allowed local agencies to issue two dozen eggs one month and three dozen eggs the next month when necessary. This monthly quantity variation, however, has caused some problems with food delivery systems, which include maintaining issuance records, pre-printing vouchers and adjusting ADP systems. Further, it contradicts the monthly supplemental nature of the Program. Other local agencies experiencing problems with egg packaging who were unable to vary amounts from month to month, resorted to categorically lowering the egg quantity for women and children. This practice is against Department policy. As a solution to these problems the food package advisory panel recommended that two dozen eggs be the designated maximum quantity in the food packages. Concurring with this recommendation, the Department proposed a maximum amount of two dozen eggs per month in the food packages for women and children.

Two hundred seventy-nine (279) commenters expressed support of the proposed egg reduction and 195 expressed opposition. Two hundred forty-one (241) of the (79 supporting comments originated from State and local agency personnel. The commenters were particularly interested in the elimination of various adminstrative problems associated with food delivery and packaging. Many commenters believed that two dozen eggs per month would be sufficient as a dietary supplement.

One hundred twenty-two commenters opposing the egg reduction expressed concern about participants' decreased intake of eggs. Those opposed to the reduction expressed the opinion that administrative problems are not valid reasons for reducing the egg allotment. Many of these commenters expressed concern that eggs are too acceptable and economical to be reduced in quantity. One hundred and three (103) commenters recommended a three

dozen maximum amount to solve administrative problems and enhance the food packages.

The Department realizes that eggs contain varying amounts of all the target nutrients in the WIC Program except vitamin C, as well as essential vitamins, minerals and fatty acids. The Department also agrees with the comments of those opposing the reduction, who maintain that the egg is an economical, versatile, highly popular and readily available food.

After considering all of the above factors, the Department has decided to change the position taken in the proposed regulations and to allow State agencies the option of establishing a maximum egg allotment of either two or two and one-half dozen eggs for the food packages for women and children.

The practice of issuing two and one-half dozen over the course of two months (i.e., two dozen one month and three dozen the next) will no longer be allowed. Some State agencies that used this approach in the past to avoid the problems of splitting cartons experienced other problems with vouchers, issuance and programming. Since State agencies have the option to issue two dozen eggs as the authorized maximum amount, this practice is no longer necessary. Further, an allotment of three dozen eggs in any one month contradicts the monthly supplemental nature of the Program. Given the supplemental nature of the program, the Department considers 36 eggs in one month excessive since it provides more than one egg a day. For this reason, and to avoid problems with food delivery systems, the Department will not allow the allotment to vary from month to month.

The Department did not raise the allotment to three dozen every month, as 103 commenters recommended, mainly for cost reasons. Raising the allotment to 3 dozen eggs in the packages for women and children would increase the cost of these packages approximately 30 to 50 cents. Costwise, the decrease in the egg allotments of those States lowering their maximum egg quantity along with the decreases in other WIC food allotments as set forth in these regulations, would help offset the cost of adding new foods to the food packages.

A maximum of two or two and one-half dozen eggs per month is in keeping with the supplemental nature of the Program because 24 or 30 eggs per month, along with the other WIC foods, are sufficient as a deitary supplement allowing almost one egg a day. Furthermore, because of the low bioavailability of iron in eggs, there is no significant decrease in available iron in the food packages resulting from allowing States to issue two dozen eggs. Information from the State agencies indicates that for 36 State agencies, this need not result in any change in current operations. These 36 State agencies are already authorizing either two dozen or two and one-half dozen eggs a month. There is currently one State agency issuing only one dozen eggs a month which will be required to at least double its maximum prescription for eggs. Some other State agencies currently prescribing two dozen eggs one month and three dozen the next may either retain the same quantity of eggs by prescribing two and one-half dozen each month, or slightly reduce the egg allotment by prescribing two dozen.

Juice—Quantities. The Department proposed allowing 92 fluid ounces of single strength juice in the food package for infants, 138 fluid ounces of single strength juice in the food package for children with special dietary needs, 276 fluid ounces of single strength juice in the food packages for children and pregnant and breastfeeding women and 184 fluid ounces of single strength juice in the food package for non-breastfeeding post partum women. Frozen concentrated juice was proposed to be allowed in all food packages, the reconstituted volume not exceeding the amount authorized for single strength juice.

One hundred sixty-nine (169) commenters addressed the issue of juice quantities; 112 opposed the proposal as written regarding the amounts of juice provided in the food packages. Most of the opposing commenters cited the discrepancy between the maximum amount of single strength juice a participant may receive and the maximum amount of frozen concentrated juice possible. They were concerned that due to packaging, participants who select frozen concentrated juice would not be able to receive the full authorized amount of juice. The opposing commenters recommended that juice quantities be specified to allow for the difference between single strength juice and reconstituted frozen concentrated juice.

Under previous regulations, participants who chose all single strength juice received slightly more juice than participants who chose all frozen concentrated juice. This was due to differences in packaging. For example, although a pregnant woman could receive the full authorized 276 fluid ounces of juice if single strength juices were used, she could receive only 264 fluid ounces of reconstituted juice if frozen concentrated juice were used. Considering that frozen concentrated juice is usually slightly less expensive than single strength juice, the Department does not believe it is appropriate to authorize a greater quantity of single strength juice than frozen concentraged juice.

In an effort to maxmize food benefits in relation to costs and support nutrition education on economical food buying practices, the Department has decided to make an additional allowance for frozen concentrated juice quantities. The final rule maintains the proposed maximum amounts of single strength juice, but slightly increases the maximum amounts of reconstituted frozen concentrated juice. The maximum amounts of reconstituted frozen concentrated juice authorized were determined based on the reconstituted volume of 12 ounce cans of frozen concentrated juice.

Fifty-three commenters specifically requested that the food package for children with special dietary needs contain the same amount of juice as the package for children. This package is designed to supplement the diets of participants who primarily need formulas. In addition, the amounts of juice and formula provided contain adequate levels of vitamin C for these participants. Therefore, the juice quantity in the special package will remain as proposed.

Maximum Amount of Juice per Package*

Infants 4 through 12 Months:	
Infant juice	63 fluid oz. (1.9 liters).
Frozen concentrated juice	96 fluid oz. (2.8 liters) (reconstituted).
Single strength juice	92 fluid oz. (2.7 liters).
Children/Women with Special Dietary Needs:	
Frozen concentrated juice	144 fluid oz. (4.3 liters) (reconstituted).
Single strength juice	138 fluid oz. (4.1 liters).
Children 1–5 Years:	
Frozen concentrated juice	288 fluid oz. (8.5 liters) (reconstituted).
Single strength juice	276 fluid oz. (8.2 liters).
Pregnant and Breastfeeding Women:	
Frozen concentrated juice	288 fluid oz. (8.5 liters) (reconstituted).
Single strength juice	276 fluid oz. (8.2 liters).
Post partum Women:	
Frozen concentrated juice	192 fluid oz. (5.7 liters) (reconstituted).
Single strength juice	184 fluid oz. (5.4 liters).

*Combinations of single strength and frozen concentrated juice may be issued as long as the total volume does not exceed the amount specified for single strength juice.

Additional Foods—Peanut Butter and Mature Dry Beans or Peas. The Department proposed adding one pound of mature dry beans or peas or 18 ounces of peanut butter to the food packages for children and pregnant and breastfeeding women. In the past, the Department has received requests to expand the variety of foods in the food package. Mature dry beans and peas

and peanut butter have been requested frequently. A vast majority of commenters supported the proposal to include these foods. Of the 748 comments on peanut butter, 614 supported its inclusion. Of the 669 comments on mature dry beans or peas 510 supported their inclusion. The primary reasons cited by the commenters in support of the addition of both peanut butter and mature dry beans or peas were their nutritional value and their acceptability to WIC participants.

An approximate cost increase ranging from $0.63–$1.49 (depending on the item purchased) would occur in the packages for children and pregnant and breastfeeding women if mature dry beans or peas or peanut butter were added. This increase in cost would be offset by the reductions in other foods in certain food packages. As the commenters indicated, the addition of those food items to the food packages would supply protein, iron and another source of micronutrients to participants. The expanded variety of foods would also support nutrition education principles. Because peanut butter has a relatively high fat content, the Department carefully considered the issue of the fat content of the food packages, as described in detail in a previous section of this preamble. The Department decided that it would be inappropriate to restrict the fat content of the food packages for all participants. The option of providing dry beans or peas instead of peanut butter provides an alternative for participants who should restrict their consumption of fat.

To increase food variety and enhance the nutrient value of the food packages, the Department has decided to add mature dry beans and peas or peanut butter to the food package for children and the food package for pregnant and breastfeeding women.

Additional Foods—Whole Wheat Bread. In the discussion on the adequacy of some micronutrients and fiber in the food packages in the preamble to the proposed regulations, the Department discussed the possibility of adding 2 pounds of whole wheat bread in the food packages for children and pregnant and breastfeeding women. However, the Department was concerned about the acceptability of whole wheat bread and availability of whole wheat bread in rural areas. Therefore, rather than proposing a change, the Department requested comments on the inclusion of 2 pounds of whole wheat bread in the food packages for pregnant and breastfeeding women and children, especially in relation to acceptability and availability.

Approximately 583 commenters addressed this issue, 395 of whom were in opposition to adding whole wheat bread to the food packages. The major reasons for opposition were administrative considerations such as vendor and participant monitoring. Vendors and participants could be confused by the labeling on various types of bread and it would be easy for them to mistakenly select a bread with a label which implies 100 percent whole wheat, but which does not qualify. Many commenters also questioned the acceptability of whole wheat bread to participants. Commenters emphasized the fact that the WIC Program is a supplemental food program, not a total dietary program. They also expressed concern that the addition of whole wheat bread, along with peanut butter or dry beans, would increase the cost of the food packages substantially, limiting the number of participants served. Commenters also mentioned the short shelf life of bread and storage problems which could result in waste.

Given the considerations mentioned above, the Department has decided not to add whole wheat bread to the food packages. Increased consumption of foods containing whole grains and other foods containing dietary fiber shall be encouraged through nutrition education.

Additional Foods—Vegetables. Out of concern about the adequacy of some micronutrients and fiber in the food packages, the Department discussed the addition of vegetables in the preamble to the proposed regulations. In its discussion on vegetables, the Department requested input from the public on this issue, including comments on the provision of vegetables to pregnant and breastfeeding women and children, the types of vegetables which should be provided and the quantities of vegetables which would be appropriate.

Of the 608 commenters addresssing the vegetable issue, 407 opposed the provision of vegetables in the food packages. Major reasons for opposition were associated with the fact that including vegetables would complicate program administration at all levels. Defining an acceptable vegetables list would be difficult and listing specific vegetables on vouchers would be cumbersome. Monitoring vendors to ensure only authorized vegetables are provided to participants would be difficult and, in areas where dairies are used for home delivery, it might not be possible to provide vegetables.

Commenters also cited the supplemental nature of the WIC Program, stating that the food packages cannot be expected to provide for all nutrient needs. Many commenters expressed concern that vegetables would not be well accepted by participants. They said not only do participants have a variety of taste preferences, but the most nutritious vegetables seem to be the least popular. Commenters were also concerned about the cost of vegetables, which, along with peanut butter and mature dry beans or peas, could increase the cost of the food packages and limit the number of participants served. Vegetable costs and availability fluctuate seasonally. The availability of vegetables also varies in different parts of the country. Storage of fresh and frozen vegetables could present problems, and therefore could result in considerable waste. Other major concerns expressed were that the vegetables received by WIC participants would be consumed by other family members; that canned, frozen and fresh vegetables all vary in nutrient content; and that methods of cooking affect their nutritional value. Some commenters also expressed concern about the high salt content of canned vegetables. The most prevalent recommendation made by the commenters was that nutrition education emphasizing increased vegetable consumption be provided in place of vegetables themselves.

Given the considerations cited above, the Department has decided not to add vegetables to the food packages. Increased consumption of vegetables shall be encouraged through nutrition education.

Adult Cereals. Previously, the Department required the cereals provided to women and children participants contain a minimum of 45 percent of the USRDA for iron. The Department proposed to reduce the iron requirement for cereals to 25 percent of the USRDA for iron for participants who do not exhibit signs of iron deficiency at certification, but to maintain the iron requirement for cereals at 45 percent of the USRDA for iron for participants who do exhibit signs of iron deficiency at certification. Additionally, the Department proposed establishing a limit of 6 grams of sucrose and other sugars per ounce of dry cereal. Other changes in the cereal requirements which the Department considered, but did not propose were discussed in the preamble to the proposed regulations and included restrictions on highly fortified cereals, cereals containing artificial flavors and colors and the provision of whole grain cereals regardless of iron content.

After careful review of the evidence and consideration of all comments, the

Department decided to require that cereals provided to all women and children participants contain a minimum of 45 percent of the USRDA for iron and not more than 6 grams of sucrose and other sugars per ounce of dry cereal. In making the decision on the iron and sugar requirements, the Department considered comments and information available on the prevalence of iron deficiency in the target population, the effectiveness of the WIC Program in relation to iron nutriture in the target population, the iron content of the food packages and the bioavailability of iron in cereals, the acceptability and availability of cereals, and the scientific evidence on the association of sugar with dental caries.

Comments on Iron Content of Adult Cereals. The Department received approximately 700 comments on the proposed change in the iron requirement for cereals; 181 in favor and 519 opposed. Commenters opposed to the proposed rule stated that two iron levels would be confusing to participants, vendors and local agency staffs and that there would be administrative problems associated with implementing the rule. Administrative problems cited included voucher issuance, program monitoring and vendor training and monitoring. Furthermore, it would be difficult to ensure that iron deficient participants would purchase or consume cereals containing 45 percent of the USRDA for iron, especially in a family with one iron deficient participant and one non-iron deficient participant. Two hundred and sixty (260) comments were received recommending that the iron requirement be maintained at 45 percent of the USRDA for iron for all participants and 138 comments were received recommending that the iron requirement be reduced to 25 percent of the USRDA for iron for all participants. Commenters in favor of maintaining the iron requirement for cereals at 45 percent of the USRDA for iron stated that lowering the iron requirement is contrary to the WIC Program's goal as a preventive health program. Iron deficiency is a major nutritional problem among the WIC Program target population, and a lower iron requirement may not help boarderline participants. Commenters in favor of lowering the iron requirement for cereals to 25 percent of the USRDA for iron stated that there is a need for a larger variety of cereals and claimed that currently authorized cereals are not acceptable to participants.

Iron Deficiency in the Target Population. Several national studies and surveys have shown that iron deficiency is a major nutritional problem among the WIC Program target population. *The Ten State Nutrition Survey* reported a high prevalence of low hemoglobin levels, particularly among the lowest income groups. Low hemoglobin values were believed to be due primarily to iron deficiency because of the age distribution and low iron consumption indicated by dietary information. (*58*) The study *Nutritional Status of Preschool Children in the United States (Preschool Nutrition Survey)* found evidence of low hemoglobin levels among preschool children of lower socioeconomic status. (*59*)

Impact of WIC on Iron Status. Studies which have been performed to evaluate the effectiveness of the WIC Program indicate improvement in iron nutrition with participation in the program. The University of North Carolina performed a medical evaluation of the WIC Program at 19 local agencies in 14 States. The investigators concluded that there was a consistent increase in hemoglobin levels and a reduction in the prevalence of anemia in infant and children participants. Additionally, an increase in mean hemoglobin concentration and a reduction in the anemia rate was reported for pregnant and postpartum women. (*60*) A study performed on WIC participants in Massachusetts showed similar results. (*61*) A number of State and local agencies have also reported decreases in the prevalence of anemia in the target population after participation in the WIC Program.

At the request of the Department, the Center for Disease Control (CDC) used data from its Nutrition Surveillance System to estimate some nutritional effects of the WIC Program. On the basis of this data, CDC reported that children entering the WIC Program have a high prevalence of anemia, presumably caused by iron deficiency, and that children enrolled in the program for one year experience considerable improvement in their hemoglobin and hemoatocrit values. (*62*)

Based on this information, it appears that WIC has a positive impact on the iron status of participants. Whether this apparent improvement is due to a specific component of the WIC Program or to the freeing up of funds for participants to purchase additional foods which are good sources of iron is not currently known. However, because cereals are the principal source of bioavailable iron in the WIC food package, they may be a significant factor in the reported improvements in iron status of WIC participants.

Iron Content of Food Packages. As stated above, cereals are the major source of iron in the WIC food packages. Therefore, a decrease in the iron requirement for cereals from 45 to 25 percent of the USRDA would have a significant effect on the quantity of iron provided by the food packages. The following calculations of the iron content of the food packages were performed using the iron content of cereals containing 45 percent and 25 percent of the USRDA for iron. Since these levels would be minimum requirements for cereals, the values for the iron content of the food packages expressed below represent minimum values. Participants selecting more highly fortified cereals would obtain a higher percentage of their requirement for iron.

With a minimum iron requirement for cereals of 45 percent of the USRDA for iron, both the previous and proposed food packages for children and pregnant and breastfeeding women provide approximately 11 mg. of iron per day. This is equal to 75 percent of the RDA for iron for children 1–3 years of age, 110 percent of the RDA for iron for children 4 years of age and 37.5 percent of the RDA for iron for pregnant and breastfeeding women.[f] If the iron requirement for cereals were decreased to 25 percent of the USRDA, the proposed food packages for children and pregnant and breastfeeding women would provide approximately 7.5 mg. of iron per day. This is equal to 50 percent of the RDA for children 1–3 years of age, 75 percent of the RDA for children 4 years of age and 25 percent of the RDA for pregnant and breastfeeding women.[f]

Iron deficiency has been identified as a major nutritional problem among the WIC target population. Current evidence suggests that the WIC Program is having a positive impact on the iron status of

[f] The RDA's for iron for pregnant and breastfeeding women in the 1974 edition of the *Recommended Dietary Allowances* are 18+ and 18 mg. of iron per day, respectively. (*63*) The 1980 edition of *Recommended Dietary Allowances* does not specify dietary requirements for iron for pregnant and breastfeeding women. The Food and Nutrition Board states that, "The increased requirement (for iron) during pregnancy cannot be met by the iron content of habitual American diets nor by existing iron stores of many women; therefore, the use of 30–60 mg. of supplemental iron is recommended. Iron needs during lactation are not substantially different form those of non-pregnant women, but continued supplementation of the mother for 2–3 months after parturition is advisable in order to replenish stores depleted by pregnancy."(*64*) Therefore, 30 mg. per day was used as the RDA for iron in the calculations for pregnant and breastfeeding women. If 18 mg. of iron per day is used as the RDA for pregnant and breastfeeding women, the food packages with a minimum iron requirement for cereals of 45 percent of the USRDA would provide 67 percent and the proposed food package with a minimum iron requirement for cereals of 25 percent of the USRDA would provide 44 percent of the RDA for iron for pregnant and breastfeeding women.

participants. Because the percent of the RDA for iron provided by the food package would be substantially reduced if cereals providing 25 percent of the USRDA for iron rather than 45 percent were offered, the ability of the WIC Program to directly affect the iron status of participants might be significantly weakened under such a rule. Based on these considerations, retaining the requirement that cereals provide at least 45 percent of the USRDA for iron appears to be advantageous from a nutritional standpoint.

Bioavailability of Iron. Although authorizing cereals fortified at 25 percent of the USRDA for iron in the WIC food packages would reduce the iron content of the food packages considerably, several researchers have come to the conclusion that the total iron content of the diet is a relatively poor indicator of the adequacy of the diet with regard to iron. (*65*) This is evidenced by the fact that there is a high prevalence of anemia in some countries where there is also a high intake of dietary iron. (*66*) A high iron intake does not automatically eliminate anemia. The relevant factor to consider in assessing dietary adequacy is not only how much total iron is consumed, but more importantly, how much is absorbed. A recent study found that the addition of an egg to breakfast increased the iron intake of individuals from 2.8 to 4.1 mg.; however, the iron absorption was unchanged. (*67*) Therefore, the iron content in the body was unaffected. These findings affirm the fact that dietary iron has to be evaluated according to its availability rather than solely on the absolute iron content of the food.

The amount of iron in a food that is available for absorption is influenced significantly by the form of iron. The Department has received information on the forms of iron used to fortify cereals from all but one of the major cereal manufacturers. (*68*) Of the 12 cereals fortified at or above 45 percent of the USRDA for iron for which the Department has information on the form of iron used, 8 are fortified with ferric orthophosphate and 4 are fortified with hydrogen reduced iron. Four of the cereals fortified at or above 45 percent of the USRDA with ferric orthophosphate and all of the cereals fortified at or above 45 percent of the USRDA with hydrogen reduced iron contain not more than 6 grams of sucrose and other sugars per ounce. Of the 19 cereals fortified at 25 percent of the USRDA for iron for which the Department has information on the form of iron used, 3 are fortified with ferric orthophosphate, 10 are fortified with hydrogen reduced iron, 5 are fortified with electrolytic iron, and one is fortified with ferrous fumarate. Three of the cereals fortified at 25 percent of the USRDA with hydrogen reduced iron, one of the cereals fortified at 25 percent of the USRDA with electrolytic iron and the cereal fortified at 25 percent of the USRDA with ferrous fumarate contain not more than 6 grams of sucrose and other sugars per ounce.

The bioavailability of iron is generally expressed as a relative biological value (RBV). Ferrous sulfate is used as a standard of comparison and assigned an RBV of 100. The RBV for ferric orthophospate has been reported to be 3 to 46, the RBV or hydrogen reduced iron has been reported to be 18 to 54, the RBV for electrolytic iron has been reported to be 45 to 76, and the RBV for ferrous fumarate has been reported to be 95. (*69*)

Based on the RBV's for different forms of iron and the amount of iron in a cereal fortified at 45 and 25 percent of the USRDA for iron, it is possible to get an indication of the amount of iron available for absorption from cereals. Data provided by industry indicate that some cereals containing 25 percent of the USRDA for iron are fortified with forms of iron which are generally considered to have higher bioavailabilities than the forms of iron used to fortify most cereals containing 45 percent or more of the USRDA for iron. However, because bioavailabilities of the different forms of iron used to fortify cereals vary and bioavailability is affected not only by the form of iron used to fortify the cereals, but also by chemical and physical properties of the iron and other factors such as components of the food, (*70*) it is not possible to make definitive statements about the bioavailability of iron from different cereals. Additional information on specifications for the forms of iron used in fortification would have to be supplied by the industry and research would have to be performed by the Department to substantiate such statements.

Although the Department recognizes that the issue of iron fortification of cereal will remain a controversial one, it has decided to maintain the minimum iron requirement for cereals authorized for use in the WIC Program at 45 percent of the USRDA for iron. The Department does not believe it has sufficient information at this time on the bioavailability of iron from cereals fortified at 25 and 45 percent of the USRDA for iron to lower the iron requirement for cereals on the basis of iron bioavailability. Data provided by industry indicate that some cereals containing 25 percent of the USRDA for iron are fortified with forms of iron which are generally considered to have higher bioavailabilities than the forms of iron used to fortify most cereals containing 45 percent or more of the USRDA for iron. Therefore, FNS has requested the Science and Education Administration, USDA, to perform research needed to make a determination of whether the bioavailability of iron from a number of cereals fortified at 25 percent of the USRDA for iron is better than the bioavailability of iron from most cereals fortified at or above 45 percent of the USRDA for iron. When information from these studies becomes available, the Department will reassess the issue of the iron requirement for cereals provided through the WIC Program.

Acceptability of Cereals. The issue of acceptability of authorized cereals was raised by 147 commenters in response to the proposed change in the iron requirement. Of these, 138 stated that there was a need for more variety in authorized cereals and that the cereals authorized under the previous regulations are not sufficiently acceptable to participants.

The most substantive data on the acceptability of cereals authorized in WIC includes information from a report on the WIC Program delivery system, small scale surveys and interviews with participants.

In 1976, the Urban Institute performed a study to evaluate the WIC Program delivery systems. As part of this study, participants were interviewed to obtain information on satisfaction with the foods in the WIC packages. These interviews revealed some participant dissatisfaction with authorized cereals. According to the report, 23 percent of the participants surveyed requested that cereal be dropped from the food package or that the amount provided be decreased. (*71*)

Small scale surveys conducted by State or local agencies indicate some dissatisfaction with cereals. A survey conducted in Tennessee in 1979 showed that 10 percent of the participants do not use the WIC cereals. (*72*) Another small scale survey from Rhode Island revealed that 13 percent of WIC children participants do not eat the cereals provided. (*73*)

Interviews with participants at local agencies in California, Washington, Oregon, Arizona, and Nevada performed by the FNS Western Regional Office in 1979 also indicate some problems with the acceptability of cereals currently authorized in the WIC Program. When

asked about the food package, some participants criticized the types of cereals provided and expressed a need for a wider selection of cereals.

Since the acceptability of authorized cereals could be a reflection of the acceptability of cereals in general, as well as a reflection of the acceptability of cereals meeting Program requirements, it was important to consider data which are available on cereal consumption in general. An analysis of data from the *Health and Nutrition Examination Survey* on cereal consumption by children 1–5 years of age revealed that 8.4 percent seldom or never eat cereal, 56.7 percent eat cereal 1–6 times per week and 35 percent eat cereal one or more times a day. For adults 18–44 years of age, 53.8 percent seldom or never eat cereal, 38.1 percent eat cereal 1–6 times per week and 8.1 percent eat cereal one or more times a day. (*74*) The WIC food package includes sufficient cereal to provide more than one serving per day. Therefore, lack of acceptability of authorized cereals could at least partially be due to the fact that many adults seldom or never eat cereal and most children and adults do not eat cereal in the quantities provided through the WIC food packages.

Given that the level of acceptance of cereals in general may not be high in some groups, it was important to consider whether the allowance of cereals that meet only 25 percent of the USRDA for iron rather than 45 percent would substantially improve the variety and acceptability of authorized cereals.

The Department examined approximately 100 cereals that are currently available on the commercial market in order to determine the impact the proposed sugar and iron requirements would have on the number of cereals authorized. Of these, 20 contain a minimum of 45 percent of the USRDA for iron. With a sugar limitation of six grams of sucrose and other sugars per ounce of cereal (see Sugar Content of Cereals section), 15 cereals would be authorized at 45 percent of the USRDA for iron and 29 cereals would be authorized at 25 percent of the USRDA for iron. Some of these cereals, however, are not available in all areas of the country. Information from 60 State agencies indicates that with the current requirement that cereals contain a minimum of 45 percent of the USRDA for iron, approximately six cereals are available in at least 50 State agencies. Twenty-nine (29) of these State agencies already restrict the use of highly sugared cereals. With a sugar limit of six grams of sucrose and other sugars per ounce, one cereal previously allowed in at least 20 State agencies would not be authorized. Thus, both the proposed sugar restriction and the 45 percent USRDA iron requirement limit to a substantial degree the total number of authorized cereals.

Data which provide an indication of the effect of lowering the iron requirement and establishing a sugar limit would have on acceptability of cereals are available from two sources, the *WIC Particpant Profile Survey* and comments submitted by the Southern Illinois University in response to the proposed regulations.

The *WIC Participant Profile Survey* was conducted by FNS in 1978. As part of this survey, participants were asked to name their two favorite cereals on the market. The ten most frequently named favorite cereals included four cereals fortified at or above 45 percent of the USRDA for iron. If the iron requirement for cereals were lowered to 25 percent of the USRDA for iron, six authorized cereals would be included in the list of ten favorites. With a sugar limitation of six grams of sucrose and other sugars, the list of ten favorite cereals would include four authorized cereals if the iron requirement were maintained at 45 percent of the USRDA for iron and five WIC cereals if the iron requirement were lowered to 25 percent of the USRDA for iron. (*75*)

The Southern Illinois University at Carbondale has provided the Department with information on reported preferred cereal usage by WIC clients in Illinois. Although the cereals which were reported as preferred cereals were not exactly the same as those named as favorites in the *WIC Participant Profile Survey*, the numbers of cereals meeting the iron and sugar requirements considered which were among the ten most frequently reported preferred cereals were the same. Additionally, an analysis of 24-hour dietary recalls of 1,100 WIC participants in Southern Illinois revealed that approximately 48 percent of participants had not consumed cereal in the preceding 24 hours; approximately 26 percent of participants consumed cereals containing 45 percent or more of the USRDA for iron; approximately 10 percent of participants consumed cereals containing 25–44 percent of the USRDA for iron and approximately 17 percent of participants consumed cereals containing less than 25 percent of the USRDA for iron. (*76*) Therefore, if cereals containing 25 percent of the USRDA for iron were authorized, approximately 10 percent of WIC participants in Illinois would probably eat them. However, the authorization of these cereals may not have any effect on cereal consumption by the 65 percent of participants who do not eat cereals or choose to eat cereals fortified at less than 25 percent of the USRDA for iron.

Thus, while reducing the iron requirement for cereals to 25 percent of the USRDA would increase the total number of cereals authorized, the number of most preferred cereals offered would not be substantially increased. Moreover, the improvements in general acceptability that would be brought about by such a change appear to be relatively small. This is particulary true when the significant nutritional reasons for maintaining the higher iron requirement discussed above are taken into consideration.

The principal reason for lowering the iron requirement would be to improve acceptability of cereals. However, although the Department believes lowering the iron requirement for cereals may improve acceptability, at this time the Department does not know whether it actually would, or if it did, to what extent lowering the iron requirement for cereals would improve acceptability. The Department intends to perform a study to assess the impact lowering the iron requirement for cereals would have on acceptability. In the meantime, the significant nutritional reasons for maintaining the higher iron requirement discussed above outweigh the modest improvements in acceptability that might result from a lowered iron requirement. For these and administrative reasons the Department has decided to maintain the minimum iron requirement for cereals authorized for use in the WIC Program at 45 percent of the USRDA for iron.

Comments on Sugar Content of Adult Cereals. Approximately 490 comments were received on the proposed sugar requirement. Of those, 389 favored the establishment of a maximum level for sugar in WIC cereals. Many of these commenters stated that the rule would support the nutrition education goals of the Program. Some commenters reiterated concerns about the association between excessive sugar consumption and obesity and dental caries. Several people commented on the actual sugar level that was proposed. The majority of those who commented on this point felt that a lower sugar level should be established. Some commenters called the "six grams per ounce" value arbitrary. Commenters who were opposed to the proposed sugar requirement argued that the rule is not based on conclusive scientific evidence and cited several studies

which they said show there is no correlation between tooth decay and the consumption of presweetened cereals. Also, they pointed out that there is no proof that sugar consumption causes obesity. They all discussed the sugar content of presweetened cereals in relation to the sugar content of other foods. They also questioned the Department's authority to impose a sugar limitation and suggested that consumers be allowed to make informed choices on their own, based on product label information. The Department feels that disallowing highly sugared cereals enables the food packages themselves to remain consistent with the goals of nutrition education and teaching participants economical and nutritious food buying patterns. The scientific evidence on the association of sugar and dental caries, and the scientific basis for the sugar requirement are discussed in detail in the section of this preamble dealing with the sugar content of the food packages. The other concerns of commenters are also addressed there and are not repeated in this section.

Adult Cereals—Highly Fortified. In the preamble to the proposed regulations the Department stated it would not restrict highly fortified cereals for 1–3 year olds. The Department asked for comments on this issue. Of 227 comments on the inclusion of highly fortified cereals, 132 opposed including these cereals in the food package, because of labeling problems and nutrition education principles. When it considered restricting the issuance of highly fortified cereals, the Department was mainly concerned about toxicity and nutrition education goals. However, the danger of toxicity from use of these cereals is minimal. FDA did not believe the levels of vitamins A and D in these cereals were high enough to cause concern about toxicity. (*77*) Restricting authorized cereals which contain 100 percent of the USRDA for one or more nutrients would eliminate five cereals for 1–3 year olds to choose from. The Department has decided to continue allowing these cereals and to let the competent professional authority use discretion in issuing them.

Adult Cereals—Artificial Flavors and Colors. In the preamble to the proposed regulations the Department stated it would continue to allow the inclusion in the food packages of cereals containing synthetic flavors and colors. Commenters were almost evenly divided in favor of or in opposition to this decision. At present, the evidence relating artificial flavors and colors to health and behavior problems in children is not sufficient to regulate in this area. Further, the artificial flavors and colors used in cereals on the market have been approved by FDA. The Department, therefore, has decided to continue allowing cereals regardless of whether or not they contain artificial flavors and colors. If the competent professional authority is concerned about a participant's consumption of products which contain synthetic flavors or colors, he can advise the participant of possible alternatives through nutrition education.

Adult Cereals—Provision of Whole Grain Cereals Regardless of Iron Content. In the preamble to the proposed regulations, the Department proposed the authorization of only those whole grain cereals which meet the iron requirement and sugar limitation. Seventy percent of 130 comments on this subject opposed the inclusion of wholé grain cereals regardless of iron content, either because the WIC Program is supplemental in nature or the provision of cereals below the required iron level would contradict the purpose of WIC as a preventive and therapeutic program.

Allowing whole grain cereals regardless of iron content would drastically reduce the amount of iron provided by the food packages. Additionally, there are no standards of identity for whole grain cereals, which presents problems when defining acceptable cereals. Therefore, the Department has decided to authorize only those whole grain cereals which meet the iron requirement and sugar limit for all cereals.

Cereals which the Department knows currently meet the iron requirement and sugar limit for cereals authorized for use in the WIC Program are listed.

Cereal *	Manufacturer	Iron [1]	Sugar [2]
Buc Wheats	General Mills	50	5
Chocolate Malt-o-Meal	Malt-o-Meal	45	0
Concentrate	Kelloggs	80	3
Corn Total	General Mills	100	8
Country Corn Flakes	General Mills	45	3
Cream of Wheat	Nabisco	45	0
Fortified Oat Flakes	Post	45	6
Kaboom	General Mills	45	6
Kix	General Mills	45	2
Mix and Eat, Regular	Nabisco	45	8
Most	Kelloggs	100	6
Product 19	Kelloggs	100	3
Quick Malt-o-Meal	Malt-o-Meal	45	0
Smart Start	Kelloggs	100	4
Total	General Mills	100	8

* Kellogg's 40% Bran Flakes has been reformulated. The reformulated product contains 45% of the USRDA for iron and 5 grams of sugar per ounce. Kellogg's will begin distribution in December 1980.
[1] Percent of USRDA.
[2] Grams per ounce.

The Department acknowledges that this list may be incomplete. Other cereals which meet the iron and sugar requirements for cereals defined in this regulation will be added to the list. Additionally, a change in the formulation of a cereal included in the list will result in that cereal being deleted from the list of acceptable cereals if the change results in the cereal no longer meeting the iron and sugar requirements for cereals defined in this regulation. Therefore, the Department requests industry to keep it updated on the composition of cereals. Information should be sent to the Supplemental Food Programs Division, FNS, at the address provided at the beginning of the preamble.

Substitutions. Public Law 95–627 grants the Secretary the authority to approve a State agency's plan to substitute different foods which are nutritionally equivalent to the authorized supplemental foods in order to allow for different cultural eating patterns. This section of the legislation was written primarily to permit areas outside the continental United States to operate a WIC Program which provides foods indigenous to the area. Accordingly, the proposed regulations contained the provision that any State agency wishing to make such substitutions submit to FNS a plan for the substitution of foods in keeping with the goals of the Program. Since few commenters addressed this issue, the Department has decided to maintain the provisions of the proposal. Substitution requests will be reviewed by FNS in order to be approved.

Commodities. The proposed food package regulations included provisions for the Department to purchase and distribute, at the request of a State agency, commodity foods. Very few commenters addressed this issue. Therefore, the Department has decided to maintain the provisions of the proposal. Funds allocated to the State agency will be used to purchase and distribute commodity foods which are requested. The commodity foods available to State agencies will be equivalent in quantity and quality to those authorized supplemental foods specified in the regulations.

Note.—This final action has been reviewed under USDA procedures established in Secretary's Memorandum 1955 to implement Executive Order 12044, and has been classified "significant".

References

1. American Society for Clinical Nutrition. "Report of the Task Force on the Evidence relating Six Dietary Factors to the Nation's Health," *American Journal of Clinical Nutrition,* (Suppl.) 32 (12)(1979): 2644–2647.

2. Life Sciences Research Office, Federation of American Societies for Experimental Biology, "Evaluation of the Health Aspects of Sucrose as a Food

Ingredient," FDA Contract No. FDA 223–75–2004 (Bethesda, MD: Life Sciences Research Office, Federation of American Societies for Experimental Biology, 1976).

3. Nizel, Abraham E., "The Science of Nutrition and its Application in Clinical Dentistry," second edition (Philadelphia: W.B. Saunders, 1966).

4. Ibid.

5. Life Sciences Research Office, "Evaluation of the Health Aspects of Sucrose as a Food Ingredient."

6. U.S. Department of Health, Education and Welfare, Public Health Service, "Health United States 1979," DHEW (PHS) Publication No. 80–1232, (Washington, D.C.: U.S. Government Printing Office, 1980), p. 181.

7. Letter of comment on November 30, 1979, Proposed Rule, Special Supplemental Food Program for Women, Infants and Children, Kellogg Company, January 28, 1980.

8. Market Facts, Inc. 1979 Kellogg Consumption Study, Chicago, Illinois, 1979. (As quoted by Kellogg Company comment), ibid.

9. Bowen, W.H., S.M. Amsbaugh, S. Monell-Torrens, et al. A method to assess cariogenic potential of foodstuffs. Journal of the American Dental Association 100: 677–681. 1980.

10. Wilson, C.J. Ready-to-eat cereals and dental caries in children: a three year study. Journal of Dental Research 58(9): 1853–1858. 1979.

11. Finn, S.B. and N. Jamison. The relative effect of dental caries of three food supplements to the diet. Dissertation Abstracts #669, 1969.

12. Glass, R.L. and S. Fleisch. Diet and dental caries: dental caries incidence and the consumption of ready-to-eat cereals. Journal of the American Dental Association 88: 807–813, 1974.

13. Rowe, N.H., R.H. Anderson, and L.A. Wanniger. Effects of ready-to-eat breakfast cereals on dental caries experience in adolescent children: a three year study. Journal of Dental Research 53(1): 33–36. 1974.

14. Page, Louise and Berta Friend, "The Changing United States Diet," Bioscience, 28 (1978): 192–198.

15. Ibid.

16. Marston, Ruth M. and Betty B. Peterkin, "Nutrient Content of the National Food Supply," Food Review, U.S. Department of Agriculture; Economic, Statistics and Cooperative Service; (Winter 1980), p. 23, 24.

17. U.S. Department of Health, Education and Welfare, Public Health Service, Office of the Assistant Secretary for Health and Surgeon General, "Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention," DHEW (PHS) publication No. 79–55071 (U.S. Government Printing Office, Washington, D.C., 1979).

18. Food and Nutrition Board, National Research Council, "Recommended Dietary Allowances," Ninth Edition. (National Academy of Sciences, 1980).

19. U.S. Department of Agriculture, Food and Nutrition Service, "National School Lunch Program and School Breakfast Program, Competitive Foods," Federal Register 45 FR 6758, January 29, 1980.

20. American Society for Clinical Nutrition, "Report of the Task Force on the Evidence Relating Six Dietary Factors to the Nation's Health," pp. 2659–2662, 2739–2748.

21. U.S. Department of Health, Education and Welfare, "Health People: The Surgeon General's Report on Health Promotion and Disease Prevention."

22. Committee on Nutrition, American Academy of Pediatrics, "Salt Intake and Eating Patterns of Infants and Children in Relation to Blood Pressure," *Pediatrics*, 53 (1974).

23. Food and Nutrition Board, National Research Council, "Toward Healthful Diets," (Washington, D.C., 1980).

24. Food and Nutrition Board, "Recommended Dietary Allowances."

25. Ibid.

26. National Center for Health Statistics, "Fats, Cholesterol, and Sodium Intake in the Diet of Persons 1–74 years: United States," *Advance Data*, 54 , (1979).

27. Life Sciences Research Office, "Evaluation of the Health Aspects of Sucrose as a Food Ingredient."

28. Food and Nutrition Board, "Toward Healthful Diets."

29. Food and Nutrition Board, "Recommended Dietary Allowances."

30. Ibid.

31. Life Sciences Research Office. "Evaluation of the Health Aspects of Sucrose as a Food Ingredient."

32. National Center for Health Statistics, "Fats, Cholesterol and Sodium Intake in the Diet of Persons 1–74 Years: United States."

33. U.S. Department of Health, Education and Welfare, "Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention."

34. American Society for Clinical Nutrition, "Report on the Task Force on the Evidence Relating Six Dietary Factors to the Nation's Health," pp. 2632–2637.

35. U.S. Department of Health, Education and Welfare, "Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention."

36. Food and Nutrition Board, "Recommended Dietary Allowances."

37. Kennedy, Eileen T., "Evaluation of the Special Supplemental Food Program for Women, Infants and Children on the Prenatal Patients in Massachusetts" (Doctoral Thesis, Harvard School of Public Health. 1979).

38. Stalinski, B.F., "Living with PKU," PKU Clinic, Denver, Colorado, April 1978.

39. Menken, J., "The Health and Social Consequences of Teenage Childbearing," *Family Planning Perspectives*, 4 (3) 1972: 45–53.

40. Klerman, L.V., Adolescent Pregnancy: A New Look at a Continuing Problem. American Journal of Public Health, 70(8): 776–778. 1980.

41. General Accounting Office, Report by the Comptroller General; "The Special Supplemental Food Program for Women, Infants and Children (WIC)—How Can It Work Better?" Publication No. CED–79–55, (Washington, D.C., General Accounting Office, February 27, 1979).

42. Committee on Nutrition American Academy of Pediatrics, "Iron Supplementation for Infants," *Pediatrics*, 58 (1976): 765–768.

43. Ibid.

44. Letter of Comment on November 30, 1979, Proposed Rule, Special Supplemental Food Program for Women, Infants and Children, from Committee on Nutrition, American Academy of Pediatrics, December 28, 1979.

45. Foman, S.J., Filer, L.J., Jr., Anderson, T.A., et al.: Recommendation for Feeding Normal Infants, *Pediatrics*, 63: 52, 1979.

46. Oski, Frank A., "Iron Fortified Formulas and Gastrointestinal Symptoms in Infants—A Controlled Study," *Peditrics* (accepted for publication, 1979.)

47. Committee on Nutrition, "Should Milk Drinking be Discouraged?" pp. 576–582.

48. Fomon, Samuel J., Lloyd J. Filer, Thomas A. Anderson, and Ekhard Ziegler, "Recommendations for Feeding Normal Infants," *Pediatrics*, 63 (1979).

49. Committee on Nutrition, American Academy of Pediatrics, "Commentary on Breast-Feeding and Infant Formulas Including Proposed Standards for Formulas," *Pediatrics*, 57 (1976): 279–285.

50. Committee on Nutrition, American Academy of Pediatrics, "Pediatric Nutrition Handbook," American Academy of Pediatrics, 1979.

51. U.S. Department of Health, Education and Welfare; Public Health Service, "Health and Vital Statistics Data from the National Health Survey: NCHS Growth Curves for Children" DHEW Publication No. (PHS) 78–1650 (Washington, D.C., U.S. Government Printing Office, 1977).

52. Committee on Nutrition, "Pediatric Nutrition Handbook."

53. Committee on Nutrition, "Iron Supplementation for Infants."

54. Correspondence and telephone contact with representatives of General Foods, Kelloggs, and Quaker Oats Corporations.

55. Committee on Nutrition, "Pediatric Nutrition Handbook."

56. American Academy of Pediatrics and American of Pedodontics, "Juice in Ready-to-Use Bottles and Nursing Bottle Caries," *News and Comment*, a publication of the American Academy of Pediatrics, 29 (January 1978): 11.

57. Committee on Nutrition, "Pediatric Nutrition Handbook."

58. U.S. Department of Health, Education and Welfare, Public Health Service and Mental Health Administration, Center for Disease Control, "Ten State Nutrition Survey 1968–1970," DHEW Publication No. (HSM) 72–8130–72–8134 (Washington, D.C.: U.S. Government Printing Office, 1972), p. 11.

59. George Owen et al. "A Study of Nutritional Status of Preschool Children in the United States, 1968–1970," Pediatrics (Suppl.) 53 (1974).

60. Joseph C. Edozien, B. R. Switzer, R. B. Bryan, Medical Evaluation of the Special Supplemental Food Program for Women, Infants, and Children (WIC), Report to the Congress, 1976, p. 63.

61. Kennedy, Eileen T., "Evaluation of the Special Supplemental Food Program for Women, Infants and Children on Prenatal Patients in Massachusetts."

62. U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, "CDC Analysis of Nutritional Indices for Selected WIC Participants," December 1977, p. 8.

63. Food and Nutrition Board, "Recommended Dietary Allowances."
64. Ibid.
65. Monsen, Elaine R., et al. "Estimation of Available Dietary Iron," American Journal of Clinical Nutrition, 31 (1978): 134–141.
66. Wadsworth, G. R., Nutritional Factors in Anemia, *World Review of Nutrition and Diet*, 21: 75 1975.
67. Rossander, Lena, Leif Hallberg and Erik Bjorn-Rasmussen; "Absorption of Iron from Breakfast Meals," *The American Journal of Clinical Nutrition*, 32 (1979): 2484–2489.
68. Correspondence and telephone contact with representatives of General Foods, Kelloggs and Quaker Oats corporations.
69. Ranum, Peter M. and R. J. Loewe, "Iron Enrichment of Cereals," *The Bakers Digest*, (June 1978): 14–20.
70. Ibid.
71. U.S. Department of Agriculture, Food and Nutrition Service, "Efficiency and Effectiveness of the WIC Program Delivery System," U.S. Department of Agriculture Miscellaneous Publication No. 1338 (1976) p. 77.
72. Survey conducted by State WIC director in Tennessee in 1979.
73. Survey conducted by State WIC director in Rhode Island in 1979.
74. National Center for Health Statistics, "Selected Findings: Food Consumption Profiles in White and Black Persons 1–74 Years of Age in the United States, 1971–74," *Advance Data*, 21 (1978).
75. U.S. Department of Agriculture, Food and Nutrition Service, Supplmental Food Programs Division, "WIC Participants Profile Survey," (Washington, D.C., Food and Nutrition Service, USDA, 1979), pp. 75–83.
76. Data from the Nutrient Dietary Data Analysis Laboratory, Southern Illinois University presented in a letter of comment from Jeannette Endres, Southern Illinois University.
77. From summary of discussions held in a meeting between representatives of the Bureau of Foods, FDA and Food and Nutrition Service, USDA, December 12, 1979.

Section 246.8 is added to read as follows:

§ 246.8 Supplemental foods.

(a) *General.* This section prescribes the requirements for providing supplemental foods to participants.

(b) *State agency responsibilities.* State agencies shall:

(1) Identify foods which are acceptable for use under the Program in accordance with the requirements of this section and provide to local agencies a list of acceptable foods and their maximum monthly quantities as specified in paragraph (c) of this section; and

(2) Ensure that local agencies: (i) make available at least one food from each group in each food package listed in paragraph (c) of this section. However, this does not mean that the local agency must provide each participant with a food from each food group.

(ii) Make available to participants the supplemental foods, as authorized in paragraph (c) of this section; and

(iii) Designate a competent professional authority to prescribe types of supplemental foods in quantities appropriate for each participant, taking into consideration the participant's age and dietary needs. The amounts of supplemental foods shall not exceed the maximum quantities specified in this section:

(c) *Food packages.* There are six food packages available under the Program which may be provided to participants. The authorized supplemental foods shall be prescribed from food packages according to the category and nutritional need of the participant. The food packages are as follows:

Note.—The metric units given are mathematical conversions. If packaging practices change, the authorized food quantities will be revised accordingly.

(1) *Food Package I—Infants 0 through 3 Months.* (i) Iron-fortified infant formula, which is a complete formula not requiring the addition of any ingredients other than water prior to being served in a liquid state, and which contains at least 10 milligrams of iron per liter of formula at standard dilution which supplies 67 kilocalories per 100 milliliters; i.e., approximately 20 kilocalories per fluid ounce of formula at standard dilution. Formulas which do not meet these requirements are authorized when a physician determines that the infant has a medical condition which contraindicates the use of infant formula as described above including, but not limited to, medical conditions which contraindicate the use of iron-fortified formula, metabolic disorders, inborn errors of amino acid metabolism, gastrointestinal disorders, malabsorption syndromes, and allergies. Low-calorie formulas are not authorized solely for the purpose of managing body weight of infants. Documentation of the physician's determination of the need for a formula which does not meet the requirements described above and the specific formula prescribed shall be included in the participant's certification file.

Concentrated liquid or powdered formula shall be provided, except that ready-to-feed formula may be authorized when the competent professional authority determines and documents that there is an unsanitary or restricted water supply, that there is poor refrigeration or that the person who is caring for an infant may have difficulty in correctly diluting concentrated liquid or powdered formula.

(ii) The quantities and types of supplemental foods prescribed shall be appropriate for the participant taking into consideration the participant's age and dietary needs. The maximum quantity of supplemental foods authorized per month is as follows:

Food	Quantity
Formula:	
Concentrated liquid formula.	403 fluid oz. (11.9 l).
or	
Powdered formula.....	May be substituted at the rate of 8 lb. (3.6 kg) per 403 fluid oz. (11.9 l) of concentrated liquid formula.
or	
Ready-to-feed formula.	May be substituted at the rate of 26 fluid oz. (.8 l) per 13 fluid oz. (.4 l) of concentrated liquid formula.

(2) *Food Package II—Infants 4 through 12 Months.* (i) Formula as specified in paragraph (c)(1)(i).

(ii) Infant cereal which contains a minimum of 45 milligrams of iron per 100 grams of dry cereal.

(iii) Single strength fruit juice which contains a minimum of 30 milligrams of vitamin C per 100 milliliters; or frozen concentrated fruit juice which contains a minimum of 30 milligrams of vitamin C per 100 milliliters of reconstituted juice; or infant juice which contains a minimum of 30 milligrams of vitamin C per 100 milliliters. Issuance prior to the time when the infant can drink from a cup is discouraged. The competent professional authority shall instruct the participant's parent or guardian to feed the juice to the participant from a cup to prevent "bottle caries."

(iv) The quantities and types of supplemental foods prescribed shall be appropriate for the participant taking into consideration the participant's age and dietary needs. The maximum quantity of supplemental foods authorized per month is as follows:

Food	Quantity
Formula:	
Concentrated liquid formula.	403 fluid oz. (11.9 l).
or	
Powdered formula.....	May be sustituted at the rate of 8 lb. (3.6 kg) per 403 fluid oz. (11.9 l) of concentrated liquid formula.
or	
Ready-to-feed formula.	May be substituted at the rate of 26 fluid oz. (.8 l) per 13 fluid oz. (.4 l) of concentrated liquid formula.
Infant cereal.....	24 oz. dry (.7 kg).
Juice*:	
Single strength adult juice.	92 fluid oz. (2.7 l).
or	
Frozen concentrated juice.	96 fluid oz. reconstituted (2.8 l).

Food	Quantity
or	
Infant juice	May be substituted at the rate of 63 fluid oz. (1.9 l) of infant juice per 92 fluid oz. (2.7 l) of single strength adult juice.

*Combinations of single strength or frozen concentrated juice may be issued as long as the total volume of juice does not exceed the amount specified for single strength juice.

(3) *Food Package III—Children/Women with Special Dietary Needs.* Children and women with special dietary needs may receive the following supplemental foods if the physician determines that the participant has a medical condition which precludes or restricts the use of conventional foods *and* necessitates the use of a formula including, but not limited to, metabolic disorders, inborn errors of amino acid metabolism gastrointestinal disorders, malabsorption syndrome and allergies. The supplemental foods described below are not authorized solely for the purpose of enhancing nutrient intake or managing body weight of children and women participants. Documentation of the physician's determination of the need for a formula and the specific formula prescribed shall be included in the participant's certification file.

(i) Formula intended for use as an oral feeding and prescribed by a physician.

(ii) Cereal (hot or cold) which contains a minimum of 28 milligrams of iron per 100 grams of dry cereal and not more than 21.2 grams of sucrose and other sugars per 100 grams of dry cereal (6 grams per ounce).

(iii) Single strength fruit juice or vegetable juice, or both, which contains a minimum of 30 milligrams of vitamin C per 100 milliliters; or frozen concentrated fruit or vegetable juice, or both, which contains a minimum of 30 milligrams of vitamin C per 100 milliliters of reconstituted juice.

(iv) The quantities and types of supplemental foods prescribed shall be appropriate for the participant taking into consideration the participant's age and special dietary needs. The maximum quantity of supplemental foods authorized per month is as follows:

Food	Quantity
Formula:	
Concentrated liquid formula.	403 fluid oz. (11.9 l).
Addition*	52 fluid oz. (1.5 l).
or	
Powdered formula	May be substituted at a rate of 8 lb. (3.6 kg) per 403 fluid oz. (11.9 l) of concentrated liquid formula.
Addition*	1 lb. (.4 kg).
or	
Ready-to-feed formula.	May be substituted at the rate of 26 fluid oz. (.8 l) per 13 fluid oz. (.4 l) of concentrated liquid formula.
Addition*	104 fluid oz. (3.1 l).
Cereal (hot or cold)	36 oz., dry (1 kg).
Juice:**	
Single strength juice	138 fluid oz. (4.1 l).
or	
Frozen concentrated juice.	144 fluid oz. reconstituted (4.3 l).

*Additional formula may be issued on an individual basis provided the need is demonstrated and documented in the individual's certification file by the competent professional authority.

**Combinations of single strength and frozen concentrated juice may be issued as long as the total volume does not exceed the amount specified for single strength juice.

(4) *Food Package IV—Children 1 to 5 Years.* (i) Pasteurized fluid whole milk which is unflavored and which contains 400 International Units of vitamin D per quart (.9 liter); or pasteurized fluid skim or lowfat milk which is unflavored and which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per fluid quart (.9 liter); or pasteurized cultured buttermilk which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per fluid quart (.9 liter); or evaporated whole milk which contains 400 International Units of vitamin D per reconstituted quart (.9 liter); or evaporated skimmed milk which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per reconstituted quart (.9 liter); or dry whole milk which contains 400 International Units of vitamin D per reconstituted quart (.9 liter); or nonfat or lowfat dry milk which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per reconstituted quart (.9 liter); or domestic cheese (pasteurized process American, Monterey Jack, Colby, natural Cheddar, Swiss, Brick, Muenster, Provolone, Mozzarella Part-Skim or Whole).

(ii) Cereal (hot or cold) which contains a minimum of 28 milligrams of iron per 100 grams of dry cereal and not more than 21.2 grams of sucrose and other sugars per 100 grams of dry cereal (6 grams per ounce).

(iii) Single strength fruit juice or vegetable juice, or both, which contains a minimum of 30 milligrams of vitamin C per 100 milliliters; or frozen concentrated fruit or vegetable juice, or both, which contains a minimum of 30 milligrams of vitamin C per 100 milliliters of reconstituted juice.

(iv) Eggs or dried egg mix.

(v) Peanut butter or mature dry beans or peas, including but not limited to, lentils, black, navy, kidney, garbanzo, soy, pinto, and mung beans, crowder, cow, split and black-eyed peas.

(vi) The quantities and types of supplemental foods prescribed shall be appropriate for the participant taking into consideration the participant's age and dietary needs. The maximum quantity of supplemental foods authorized per month is as follows:

Food	Quantity
Milk:	
Fluid whole milk	24 qt (22.7 l).
or	
Fluid skim or low fat milk.	May be substituted for fluid whole milk on a quart-for-quart (.9 l) basis.
or	
Cultured buttermilk	May be substituted for fluid whole milk on a quart-for-quart (.9 l) basis.
or	
Evaporated whole milk.	May be substituted for fluid whole milk at the rate of 13 fluid oz (.4 l) per qt (.9 l) of fluid whole milk.
or	
Evaporated skimmed milk.	May be substituted for fluid whole milk at the rate of 13 fluid oz (.4 l) per qt (.9 l) of fluid whole milk.
or	
Dry whole milk	May be substituted for fluid whole milk at the rate of 1 lb (.4 kg) per 3 qt (2.8 l) of fluid whole milk.
or	
Nonfat or lowfat dry milk.	May be substituted for fluid whole milk at the rate of 1 lb (.4 kg) per 5 qt (4.7 l) of fluid whole milk.
or	
Cheese	May be substituted for fluid whole milk at the rate of 1 lb (.4 kg) per 3 qt (2.8 l) of fluid whole milk. 4 lbs (1.8 kg) is the maximum amount which may be substituted.*
Eggs:	
Eggs	2 doz or 2½ doz.
or	
Dried egg mix	May be substituted at the rate of 1.5 lb (.7 kg) egg mix per 2 doz fresh eggs or 2 lb (.9 kg) egg mix per 2½ doz fresh eggs.
Cereals (hot or cold)	36 oz, dry (1 kg).
Juice:**	
Single strength juice	276 fluid oz (8.2 l).
or	
Frozen concentrated juice.	288 fluid oz, reconstituted (8.5 l).
Legumes:	
Dry beans or peas	1 lb (.4 kg).
or	
Peanut butter	18 oz (.5 kg).

*Additional cheese may be issued on an individual basis in cases of lactose intolerance, provided the need is documented in the participant's file by the competent professional authority.

**Combinations of single strength and frozen concentrated juice may be issued as long as the total volume does not exceed the amount specified for single strength juice.

(5) *Food Package V—Pregnant and Breastfeeding Women.* (i) Pasteurized fluid whole milk which is unflavored and which contains 400 International Units of vitamin D per quart (.9 liter) or pasteurized fluid skim or lowfat milk which is unflavored and which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per fluid quart (.9 liter); or pasteurized cultured buttermilk which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per fluid quart (.9 liter); or evaporated whole milk which contains 400 International Units of vitamin D per reconstituted quart (.9 liter); or

evaporated skimmed milk which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per reconstituted quart (.9 liter); or dry whole milk which contains 400 International Units of vitamin D per reconstituted quart (.9 liter); or nonfat or lowfat dry milk which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per reconstituted quart (.9 liter); or domestic cheese (pasteurized process American, Monterey Jack, Colby, natural Cheddar, Swiss, Brick, Muenster, Provolone, Mozzarella Part-Skim or Whole).

(ii) Adult cereal (hot or cold) which contains a minimum of 28 milligrams of iron per 100 grams of dry cereal and not more than 21.2 grams of sucrose and other sugars per 100 grams of dry cereal (6 grams per ounce).

(iii) Single strength fruit juice or vegetable juice, or both, which contains a minimum of 30 milligrams of vitamin C per 100 milliliters; or frozen concentrated fruit or vegetable juice, or both, which contains a minimum of 30 milligrams of vitamin C per 100 milliliters of reconstituted juice.

(iv) Eggs or dried egg mix.

(v) Peanut butter or mature dry beans or peas, including but not limited to lentils, black, navy, kidney, garbanzo, soy, pinto and mung beans, crowder, cow, split and black-eyed peas.

(vi) The quantities and types of supplemental foods prescribed shall be appropriate for the participant taking into consideration the participant's age and dietary needs. The maximum quantity of supplemental foods authorized per month is as follows:

Food	Quantity
Milk:	
Fluid whole milk	28 qt. (26.5 liters).
or	
Fluid skim or low fat milk	May be substituted for fluid whole milk on a quart-for-quart (.9 liter) basis.
or	
Cultured buttermilk	May be substituted for fluid whole milk on a quart-for-quart (.9 liter) basis.
or	
Evaporated whole milk	May be substituted for fluid whole milk at the rate of 13 fluid oz. (.4 liter) per qt. (.9 liter) of fluid whole milk.
or	
Evaporated skimmed milk	May be substituted for fluid whole milk at the rate of 13 fluid oz. (.4 liter) per qt. (.9 liter) of fluid whole milk.
or	
Dry whole milk	May be substituted for fluid whole milk at the rate of 1 lb. (.4 kg.) per 3 qt. (2.8 liters) of fluid whole milk.
or	
Nonfat or lowfat dry milk	May be substituted for fluid whole milk at the rate of 1 lb. (.4 kg.) per 5 qt. (4.7 liters) of fluid whole milk.
or	
Cheese	May be substituted for fluid whole milk at the rate of 1 lb. (.4 kg.) per 3 qt. (2.8 liters) of fluid whole milk. 4 lbs. (1.8 kg.) is the maximum amount which may be substituted.*
Eggs:	
Eggs	2 doz. or 2½ doz.
or	
Dried egg mix	May be substituted at the rate of 1.5 lb. (.7 kg.) egg mix per 2 doz. fresh eggs, or 2 lb. (.9 kg.) egg mix per 2½ doz. fresh eggs.
Cereal (hot or cold)	36 oz., dry (1 kg.).
Juice:**	
Single stength juice	276 fluid oz. (8.2 liters).
or	
Frozen, concentrated juice	288 fluid oz., reconstituted (8.5 liters).
Legumes:	
Dry beans or peas	1 lb. (.4 kg.)
or	
Peanut butter	18 ounces (.5 kg.)

*Additional cheese may be issued on an individual basis in cases of lactose intolerance, provided the need is documented in the participant's file by the competent professional authority.

**Combinations of single strength or frozen concentrated juice may be issued as long as the total volume does not exceed the amount specified for single strength juice.

(6) *Food Package VI—Non-breastfeeding Postpartum Women.* (i) Pasteurized fluid whole milk which is unflavored and which contains 400 International units of vitamin D per quart (.9 liter); or pasteurized fluid skim or lowfat milk which is unflavored and which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per fluid quart (.9 liter); or pasteurized cultured buttermilk which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per fluid quart (.9 liter); or evaporated whole milk which contains 400 International Units of vitamin D per reconstituted quart (.9 liter); or evaporated skimmed milk which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per reconstituted quart (.9 liter); or dry whole milk which contains 400 International Units of vitamin D per reconstituted quart (.9 liter); or nonfat or lowfat dry milk which contains 400 International Units of vitamin D and 2000 International Units of vitamin A per reconstituted quart (.9 liter); or domestic cheese (pasteurized process American, Monterey Jack, Colby, natural Cheddar, Swiss, Brick, Muenster, Provolone, Mozzarella Part-Skim or Whole).

(ii) Cereal (hot or cold) which contains a minimum of 28 milligrams of iron per 100 grams of dry cereal and not more than 21.2 grams of sucrose and other sugars per 100 grams of dry cereal (6 grams per 1 oz.).

(iii) Single strength fruit juice or vegetable juice, or both, which contains a minimum of 30 milligrams of vitamin C per 100 milliliters; or concentrated fruit or vegetable juice, or both, which contains a minimum of 30 milligrams of vitamin C per 100 milliliters of reconstituted juice.

(iv) Eggs or dried egg mix.

(v) The quantities and types of supplemental foods prescribed shall be appropriate for the participant taking into consideration the participant's age and dietary needs. The maximum quantity of supplemental foods authorized per month is as follows:

Food	Quantity
Milk:	
Fluid whole milk	24 qt. (22.7 liters)
or	
Fluid skim or lowfat milk	May be substituted for fluid whole milk on a quart-for-quart (.9 liter) basis.
or	
Cultured buttermilk	May be substituted for fluid whole milk on a quart-for-quart (.9 liter) basis.
or	
Evaporated whole milk	May be substituted for fluid whole milk at the rate of 13 fluid ounces (.4 liter) per qt. (.9 liter) of fluid whole milk.
or	
Evaporated skimmed milk	May be substituted for fluid whole milk at the rate of 13 fluid ounces (.4 liter) per qt. (.9 liter) of fluid whole milk.
or	
Dry whole milk	May be substituted for fluid whole milk at the rate of 1 lb. (.4 kg.) per 3 qt. (2.8 liters) of fluid whole milk.
or	
Nonfat or lowfat dry milk	May be substituted for fluid whole milk at the rate of 1 lb. (.4 kg.) per 5 qt. (4.7 liters) of fluid whole milk.
or	
Cheese	May be substituted for fluid whole milk at the rate of 1 lb. (.4 kg.) per 3 qt. (2.8 liters) of fluid whole milk. 4 lbs. (1.8 kg.) is the maximum amount which may be substituted.*
Eggs:	
Eggs	2 doz. or 2½ doz.
or	
Dried egg mix	May be substituted at the rate of 1.5 lb. (.7 kg.) egg mix per 2 doz. fresh eggs of 2 lb. (.9 kg.) egg mix per 2½ doz. fresh eggs.
Cereal (hot or cold)	36 oz., dry (1 kg.)
Juice:**	
Single strength juice	184 fluid oz. (5.4 liters)
or	
Frozen concentrated juice	192 fluid oz., reconstituted (5.7 liters)

*Additional cheese may be issued on an individual basis in cases of lactose intolerance, provided the need is documented in the participant's file by the competent professional authority.

**Combinations of single strength or frozen concentrated juice may be issued as long as the total volume does not exceed the amount specified for single strength juice.

(d) *Use of Commodity Foods.* (1) At the request of a State agency, the Department shall purchase commodity foods for the State agency using funds allocated to the State agency. The commodity foods purchased and made available to the State agency shall be

equivalent to the foods specified in paragraph (c) of this section.

(2) The State agency shall: (i) Distribute the commodity foods to the local agency.

(ii) Ensure satisfactory storage conditions for the commodity foods, including documentation of proper insurance.

(iii) Ensure that the local agency has proper storage facilities for the commodity foods.

(e) *Substitute Foods.* (1) The State agency may submit to FNS a plan for substitution of foods acceptable for use in the Program to allow for different cultural eating patterns. The plan shall include the State agency's justification for the proposed substitution, including a specific explanation of the cultural eating patterns which require the proposed substitution and other information necessary for FNS to evaluate the plan as specified in paragraph (e)(2) of this section.

(2) FNS shall evaluate a State agency's plan for substitution of foods for different cultural eating patterns based on the following criteria: (i) *Nutritional equivalence.* Any proposed substitute food must be nutritionally equivalent or superior to the food it is intended to replace.

(ii) *Availability.* The proposed substitute must be widely available to participants in the areas where the substitute is intended to be used.

(iii) *Cost.* The cost of the substitute must be equivalent to or less than the cost of the food it is intended to replace.

(3) FNS shall make a determination on the State plan for substitution of foods for different cultural eating patterns based on the evaluation criteria specified in paragraph (2) above and the State agency's justification for the substitution. The State agency shall use substitute foods only after receiving the written approval of FNS.

(Child Nutrition Amendments of 1978, Pub. L. 95–627, Section 3, 92 Stat. 3611 et seq.)

Note.—The reporting and/or recordkeeping requirements contained herein have been submitted for approval by the Office of Management and Budget in accordance with the Federal Reports Act of 1942 and are subject to their clearance.

(Catalog of Federal Domestic Assistance Program No. 10.557, National Archives Reference Service)

Dated: November 3, 1980.

Carol Tucker Foreman,

Assistant Secretary for Food and Consumer Services.

[FR Doc. 80-35232 Filed 11-11-80; 8:45 am]

BILLING CODE 3410-30-M